

Exhibit B

1 Uncertified Rough Draft Transcript

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3 the matter of In Re Ethicon Pelvic Repair
4 System Products Liability Litigation.

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1 BY MR. DeGREEFF:

2 Q. Good morning, doctor.

3 Can you tell us your name?

4 A. Lawrence Lind, L-I-N-D.

5 Q. And Dr. Lind, you have been
6 hired as a general liability expert for
7 Ethicon in this litigation.

8 True?

9 A. Yes.

10 Q. Have you also served as a
11 case-specific expert for Ethicon in
12 various cases in this litigation?

13 A. I have.

14 Q. How many?

15 A. About four to -- four to six
16 cases.

17 Q. Have you ever been hired as an
18 expert witness for any other transvaginal

19 mesh manufacturer?

20 A. No.

21 Q. And understanding I'm not asking
22 you about consulting. I'm just asking you
23 about litigation expert.

24 A. No, I have not.

4

1 Q. Do you have an understanding of
2 what you were hired to do on behalf of
3 Ethicon in this litigation?

4 A. Yes.

5 Q. What is that?

6 A. To give opinions regarding
7 efficacy and safety of mesh and sling
8 products.

9 Q. Any particular mesh and sling
10 products or just mesh and sling products
11 generally?

12 A. So by that you mean did I
13 dedicate a deposition on the TVT where
14 we're talking about the sling family,
15 TVT-0, TVT-Abbrevio and TVT-Exact.

16 Q. Doctor, you've been deposed

17 before today?

18 A. I had a deposition on the TVT
19 and in medical malpractice cases I've been
20 deposed.

21 Q. Other than the general
22 deposition you gave on the TVT in 2017.

23 Is that right?

24 A. '17 or '18.

5

1 MS. GERSTEL: It was '17, yes.

2 BY MR. DeGREEFF:

3 Q. Other than that deposition, have
4 you been deposed on any Ethicon mesh
5 product?

6 A. Prolift.

7 Q. And that was also the general
8 deposition you gave in 2017?

9 A. Yes.

10 Q. Have you given any case-specific
11 expert depositions on behalf of Ethicon in
12 this litigation?

13 THE WITNESS: In Tays, right?

14 Did we do a deposition in Tays?

15 MS. GERSTEL: That was in New
16 Jersey. The Carolyn Tays matter in
17 New Jersey.

18 BY MR. DeGREEFF:

19 Q. So I think the answer is yes,
20 you've been deposed before?

21 A. Yes, in one case.

22 MS. GERSTEL: Could I just state
23 for the record that the 2017
24 deposition that Dr. Lind gave, it was

6

1 on TVT and Gynemesh, actually, not
2 Prolift.

3 MR. DeGREEFF: Okay.

4 BY MR. DeGREEFF:

5 Q. Have you ever been deposed
6 previously as an expert for any other
7 transvaginal mesh manufacturer?

8 A. There was a communication
9 between myself and I was working on
10 research and development for a vaginal
11 mini sling for Boston Scientific and some
12 of the feedback I gave in a research lab

13 was of interest to the counsels. So I was
14 deposed to answer questions regarding my
15 feedback on -- at the research phase of a
16 mini sling.

17 Q. And what was the mini sling
18 product?

19 A. At the time, I don't recall. I
20 don't know if it was named at the time.
21 It was early in the research and
22 development.

23 Q. So you were deposed in the
24 Boston Scientific transvaginal mesh

7

1 litigation?

2 A. Yes.

3 Q. What was the subject matter of
4 that deposition?

5 A. It was my positive and negative
6 feedback for improvements and design on
7 the device at a research and design lab.

8 Q. The design of a Boston
9 Scientific product.

10 Is that right?

11 A. Yes.

12 Q. What was your involvement in the
13 design of that Boston Scientific product?

14 A. They -- the phase that they had
15 prototypes for, they asked me to use the
16 device on cadavers and comment on the
17 handling, the ease of placing the sling,
18 potential improvement, potential problems,
19 things that could be improved.

20 Q. And you pointed out problems.

21 Is that right?

22 MS. GERSTEL: Objection.

23 A. I pointed out beneficial aspects
24 and areas that I thought might be

8

1 improved.

2 Q. What were the beneficial aspects
3 of the Boston Scientific sling that you
4 pointed out?

5 A. I thought the shape of the
6 handle was favorable for being able to
7 plant the anchor at a good angle to the
8 obturator membrane. I thought they had

9 some -- a line at the midline I thought
10 was very helpful in helping to keep the
11 sling 50 percent on each side.

12 And the remainder of the
13 positive and negatives I don't recall.
14 This was about five years ago.

15 Q. Are those two positives you just
16 pointed out, are those design aspects of
17 any of the TVT slings?

18 MS. GERSTEL: Object to form.

19 A. You know, I don't use mini
20 slings presently. So I haven't been
21 looking at them and comparing them for
22 quite a number of years. It's within the
23 aspect of slings that I look at, I don't
24 have comparisons.

9

1 Q. Well, the TVT mini slings -- the
2 TVT-S, which is the Ethicon mini sling, is
3 off the market, right?

4 A. Yes.

5 Q. So you wouldn't be using
6 something that's off the market?

7 A. Correct.

8 Q. And my question was the mini
9 slings you're talking about, for example
10 the handles, are the handles on the TVT
11 products similar?

12 MS. GERSTEL: Object to form.

13 A. I haven't seen them for several
14 years. So I wouldn't have enough recall
15 to compare them.

16 Q. Well, do you currently use TVT
17 products, TVT sling products?

18 A. Yes.

19 Q. What about the aspect you were
20 talking about with the midline --

21 MR. DeGREEFF: Strike that.

22 Q. So, this was a transobturator
23 placement device.

24 Is that right?

10

1 A. Yeah. With the mini slings,
2 it's the -- you're placing it to the
3 transobturator membrane without
4 perforating it completely. So it does go

5 to the obturator membrane, but not through
6 it.

7 Q. Is it a good or bad thing to go
8 through the transobturator membrane?

9 MS. GERSTEL: Object to the
10 form.

11 A. The key aspect in designing the
12 mini slings as I do recall giving input,
13 is that you've got to get the anchor set.
14 So it's got to go through -- you know,
15 there's an interior and a posterior aspect
16 of the obturator membrane with the muscle
17 between it. So you have to get through
18 the internal membrane for the anchor to be
19 seated nicely. Otherwise it will pull
20 out.

21 Q. Right.

22 I think you told me you've given
23 one general liability deposition on the
24 TVT and Gynecare product on behalf of

11

1 Ethicon and four to five case-specific
2 depositions on behalf of Ethicon

3 previously.

4 Is that correct?

5 A. Those are case reports.

6 MS. GERSTEL: Objection.

7 A. They have not gone to

8 deposition.

9 MR. DeGREEFF: Strike that. My

10 fault.

11 Fair point.

12 THE WITNESS: Okay.

13 BY MR. DeGREEFF:

14 Q. So, how many depositions have

15 you given total on behalf of TVM

16 manufacturers in litigation brought by

17 women against them claims complications?

18 MS. GERSTEL: Object to the

19 form.

20 A. So, there's the -- there's the

21 Gynemesh and TVT. There's the one

22 case-specific report and there's today.

23 Q. Have you ever testified at trial

24 for any manufacturer of transvaginal mesh?

1 A. No.

2 Q. Have you ever been an expert
3 witness in cases unrelated to transvaginal
4 mesh?

5 A. Yes.

6 Q. What kind of cases?

7 A. I take malpractice cases, both
8 plaintiff and defendant cases, for various
9 law firms in the area that know me and
10 decide when the problem of interest is in
11 my area.

12 Q. How many times have you been a
13 expert in med-mal cases?

14 A. I would say two or three cases a
15 year for the last ten years.

16 Q. So 20 to 30 total probably?

17 A. Yes.

18 Q. Of those 20 to 30, how many have
19 been on behalf of the plaintiff, the
20 injured party?

21 A. Two.

22 Q. And what kind of cases were
23 those?

24 A. A woman was in labor and the

1 baby was stuck and the maneuvers used to,
2 you know, panicked to get the baby out
3 were excruciatingly outside of the usual
4 protocols, and she endured premise pelvic
5 floor injury.

6 And the second one was a
7 laparoscopic case with a patient with five
8 or six previous surgeries with a bowel
9 injury. There was steps taken to verify
10 safety of a laparoscopic case in a patient
11 with a difficult abdomen.

12 Q. So, of the 20 to 30 med-mal
13 cases you've been an expert in, only two
14 of them you're the plaintiff's expert?

15 A. Correct.

16 Q. Is it fair for me to assume you
17 understand how this process works, the
18 deposition process, so we don't have to go
19 through the rules?

20 A. Absolutely.

21 Q. Okay.

22 A. I will be a good exchange
23 partner in this process.

24 Q. Perfect.

14

1 Sir, have you ever been sued?

2 A. I had -- as a resident, I was
3 named in three cases. And one of them
4 settled. The settling had nothing to do
5 with my role in the case. And the other
6 two I got dropped.

7 And since that time, I have not
8 been sued.

9 Q. What was the claim -- were the
10 three cases like companion cases or
11 something?

12 A. One was a very difficult case
13 with a mother came in sepsis in labor with
14 twins in labor, and it was clear that she
15 was septic. The vaginal delivery went
16 routinely, but the high risk maternal
17 fetal medicine doctor was suspicious that
18 she probably had group A strep and was in
19 tremendous danger of serious
20 complications, and both she and the baby
21 died.

22 Q. What were the allegations
23 against you in that case?

24 A. I don't -- they never questioned

15

1 me for anything I did wrong. I think they
2 wanted to know what my role was in surgery
3 to see if I was more involved with
4 something that might be tangible to the
5 outcome, and I assisted with the delivery
6 as a secondhand. So my role was felt to
7 be minimal.

8 The second one was a patient had
9 a abnormal bleeding after a C-section and
10 I was called with the GYN oncology team to
11 help do some artery ligation to reduce
12 bleeding and in the process of the
13 procedure, the femoral nerve was
14 compressed. So she had some lack of
15 sensation in the -- you know, we saved
16 her -- well, may have saved her life. We
17 controlled the bleeding, but in the
18 process of controlling the bleeding, we
19 kinked and caused some pressure on one --

20 the nerves to the vessels of one of her
21 legs. It was diagnosed in the recovery
22 room and she had to go back and have that
23 released, but she did fine, but she did
24 have to go back.

16

1 Q. When you serve as an expert in a
2 case, is it your goal to promote the
3 truth?

4 A. Yes.

5 Q. And not to be an advocate or
6 promoter for one side or the other?

7 A. Correct.

8 Q. You agree that an expert's
9 opinion should be unbiased and objective?

10 A. I agree.

11 Q. When you gave your opinions in
12 this litigation, you wanted to be as
13 accurate as possible.

14 Is that fair?

15 A. Yes.

16 Q. And you want to be as thorough
17 in your review of the available

18 information, documents and literature as
19 possible.

20 Correct?

21 A. Yes.

22 Q. And you wanted to make sure you
23 got all of the information and considered
24 all the information that was pertinent to

17

1 your opinions, right?

2 MS. GERSTEL: Object to the
3 form.

4 A. I would describe that -- the
5 answer to your question is yes. However,
6 as these interviews or depositions
7 continue, areas of interest where the
8 other party feels I have not been as
9 thorough have come to attention. So I
10 have continued my research and continued
11 my reading and added to my knowledge and
12 resources to be able to be more complete
13 than I was even at the time of the report.

14 Q. So, you reviewed additional
15 information after you had already issued

16 your opinions?

17 A. Yes.

18 MS. GERSTEL: Objection.

19 BY MR. DeGREEFF:

20 Q. And did you change your opinions
21 based on any of that additional
22 information?

23 A. No.

24 Q. I take it what you actually did

18

1 was just add some stuff to your reliance
2 list.

3 Is that fair?

4 MS. GERSTEL: Object to form.

5 A. Well, things were added to the
6 reliance list and some were just added to
7 my general knowledge just to enable me to
8 be more informed on issues that were
9 brought to my attention that I had
10 authority on, but not as much authority on
11 as I would like to to be authoritative at
12 a higher level.

13 Q. So following depositions, you

14 went and educated yourself better for the
15 next deposition, is what you did?

16 MS. GERSTEL: Object to the
17 form.

18 A. I had interest in being educated
19 for the sake of being educated and
20 knowledgeable for my practice and
21 teaching, as well as for the depositions,
22 yes.

23 Q. Did you want to make sure you
24 had an understanding of both sides of the

19

1 story before you gave your opinions?

2 A. Yes.

3 Q. The relevant information that
4 you'd want to consider when rendering your
5 opinions would include Ethicon internal
6 documents.

7 Is that fair?

8 MS. GERSTEL: Object to the
9 form.

10 A. That's a piece amongst a much
11 larger group of documents, which is

12 scientific literature. But those would be
13 included, yes.

14 Q. Sure.

15 And it would also include
16 medical literature?

17 A. Sure.

18 Q. Would also include standards and
19 testing performed on the products?

20 A. Yes.

21 Q. Would it include making sure you
22 understand the differences between the
23 products?

24 A. Yes.

20

1 Q. Do you agree that opinions
2 should be able to be substantiated by the
3 totality of the most relevant available
4 data and information?

5 MS. GERSTEL: Object to the
6 form.

7 A. Yes.

8 Q. As a physician, your patient's
9 safety is the most important thing.

10 Fair?

11 A. Yes.

12 Q. And would it be unfair for a
13 physician to promote a position that
14 jeopardizes the health or safety of his
15 patients?

16 A. I'm sorry. Could you repeat
17 that?

18 Q. Would it be unfair for a
19 physician to promote a position that is
20 adverse or could jeopardize the health or
21 safety of his patients?

22 MS. GERSTEL: Object to the
23 form.

24 A. If the information he was given

21

1 was incorrect, that would not be
2 appropriate.

3 Q. I think we're saying the same
4 thing, but I'm not sure. Let me ask --

5 A. I'm not sure either.

6 Q. Let me ask my question again.

7 A physician shouldn't --

8 MR. DeGREEFF: Let me ask it

9 maybe in a easy area way.

10 BY MR. DeGREEFF:

11 Q. A physician should not promote a
12 position that is adverse to the health,
13 safety and welfare of their patients.

14 Is that fair?

15 MS. GERSTEL: Object to the
16 form.

17 A. I can agree with that.

18 MR. DeGREEFF: Let's do some
19 housekeeping and mark some of this
20 stuff you brought with you here.

21 (Lind Exhibit 1, Notice to Take
22 Deposition of Lawrence Lind, MD, was
23 marked for identification, as of this
24 date.)

22

1 BY MR. DeGREEFF:

2 Q. Dr. Lind, I'm going to hand you
3 what I marked as Deposition Exhibit 1.
4 That is the notice for your deposition
5 today.

6 Have you seen that before?

7 A. Yes.

8 Q. When did you first see it?

9 A. A few weeks ago, a month ago.

10 Q. Who provided it to you?

11 A. Diana.

12 Q. That would be counsel for
13 Ethicon that's here with you today?

14 A. Counsel for Ethicon.

15 Q. And did you bring --

16 MR. DeGREEFF: In fairness to
17 you, so, you've brought some things
18 with you today, correct.

19 A. Yes.

20 Q. One of the things is a flash
21 drive, and I'm going to mark it as
22 deposition Exhibit 2.

23 (Lind Exhibit 2, flash drive,
24 was marked for identification, as of

23

1 this date.)

2 BY MR. DeGREEFF:

3 Q. Can you tell me what is on this

4 flash drive?

5 A. That is a reliance list.

6 Q. So this would be all of the
7 materials that are identified on the
8 reliance list?

9 A. Those are all the materials on
10 the existing reliance list. There are
11 materials that I reviewed since that was
12 created that are in my head that are also
13 part of my knowledge and information I
14 would share today that are not on the
15 reliance list.

16 Q. Okay. We're going to get to
17 that in a minute. I just want to make
18 sure I understand what's on the flash
19 drive.

20 The flash drive includes
21 everything that's on the written
22 supplemental exhibit list.

23 Fair?

24 A. Yes.

24

1 Q. Then you brought a couple other

2 things with you that appear to be
3 invoices.

4 Is that correct?

5 A. Yes.

6 (Lind Exhibit 3, invoice of Dr.
7 Lind dated August 29, 2017, was marked
8 for identification, as of this date.)

9 BY MR. DeGREEFF:

10 Q. Can you tell me what Exhibit 3
11 is, doctor?

12 A. This is an invoice for review of
13 relevant literature and summary of opinion
14 statements regarding the defense expert
15 report on TVT and TVT-Exact.

16 Q. So is that one of your invoices
17 with regard to preparation of your TVT
18 products expert report?

19 A. Yes.

20 Q. The general report, correct?

21 A. This would be the report we're
22 looking at today.

23 Q. Correct.

24 And this would be the bill for

1 the report regarding the general liability
2 opinions you're giving in the litigation
3 as a whole.

4 Fair?

5 Not case-specific.

6 A. Yes.

7 (Lind Exhibit 4, invoice of Dr.
8 Lind dated July 1, 2019, was marked
9 for identification, as of this date.)

10 BY MR. DeGREEFF:

11 Q. Then can you tell me what
12 Exhibit 4 is, please, doctor.

13 A. This is a bill for a
14 case-specific report. The case-specific
15 report appears to be an error. This is
16 additional records that were reviewed for
17 this preparation.

18 Q. Okay. So, Exhibit 4 is an
19 additional invoice for review of records
20 related to your general report on the TVT
21 products.

22 Fair?

23 A. Yes.

24 Q. So it says case-specific, but

1 that's an error.

2 A. Yes.

3 Q. It should be generic report?

4 A. Correct.

5 Q. Is there anything else that you
6 brought with you today?

7 A. I have my general report as it
8 was served to you.

9 Q. Okay.

10 A. I prepared just an index. It
11 just helps me when you ask me about a
12 certain topic, it lets me go to a spot in
13 my report more quickly.

14 I have a 2008 and a 2015 IFU.

15 And I have the articles that are
16 referenced in my report.

17 And I have an index of those
18 articles so I can go to them quickly when
19 we want to discuss them.

20 Q. Is everything you have in front
21 of you included on the flash drive?

22 A. I believe it is. And the flash

23 drive probably has more articles than are
24 here.

27

1 Q. Is the index included on the
2 flash drive?

3 THE WITNESS: I don't know the
4 answer to that.

5 MS. GERSTEL: It should be, but
6 I can confirm that.

7 MR. DeGREEFF: It's okay. Let's
8 just go ahead and mark it.

9 (Lind Exhibit 5, handwritten
10 Report Index of Dr. Lind, was marked
11 for identification, as of this date.)

12 MR. DeGREEFF: And I'll let you
13 continue to use it, obviously.

14 THE WITNESS: Do you want a copy
15 so you have one to keep?

16 MR. DeGREEFF: No, that's okay.

17 BY MR. DeGREEFF:

18 Q. Doctor, I've marked deposition
19 Exhibit 5.

20 Can you tell me what that is?

21 A. It's a long report, you know,
22 50-plus pages, and we're here to have a
23 several-hour discussion about what's in
24 the report, amongst other things you may

28

1 want to discuss. And it was -- I found
2 from the past experience that hunting for
3 areas that we're talking about is useful
4 to just have a one-page thing that lets me
5 go to the spot a little more quickly.

6 Q. Okay. So, this is
7 essentially -- Exhibit 5 is essentially a
8 skeleton outline of your report so that
9 you can --

10 A. Right.

11 Q. -- find things more quickly?

12 A. Right.

13 Now, I will say, for complete
14 disclosure, sometimes when we go to the
15 report, we will go to an area of the
16 report and the key thing's going to be to
17 discuss what's in that section. So
18 sometimes I have written maybe three words

19 that reminds me of what the study is
20 talking about in that section. My goal
21 there is to get to that and I say let me
22 go to the study and we've got to go
23 through the binders and find it and locate
24 it and I want to review it. I can save us

29

1 that time.

2 So there are a few words here
3 and there that just remind me of what an
4 article said.

5 Q. Okay. Fair enough.

6 So, sir, this is a pretty simple
7 question.

8 You're being paid to serve as a
9 expert witness for Ethicon in this
10 litigation.

11 True?

12 A. Yes.

13 Q. And, so, other than Exhibit 3
14 and Exhibit 4, have you sent any bills for
15 your work on the TVT product general
16 expert report?

17 A. Let me just -- may I just see
18 those one more time?

19 Q. (Handing.)

20 A. (Perusing document.)

21 I have not.

22 Q. Have you incurred any more time
23 to date that you have not billed for yet?

24 A. Yes.

30

1 Q. About how much time is that?

2 A. About 25 hours.

3 Q. Will you be billing that 25
4 hours at \$500 an hour?

5 A. I will.

6 Q. And is \$500 an hour your rate?

7 A. Yes.

8 Q. What is your rate for the
9 deposition here today?

10 A. Seven thousand five hundred.

11 Q. So it's 7,500 is your rate for a
12 full-day deposition.

13 Is that correct?

14 A. Yes, it is.

15 Q. Okay. So, check my math, but
16 that's about another \$20,000?

17 A. About right.

18 Q. So that would be initially to
19 the 10,500 and 16,000 that are set forth
20 in Exhibits 4 and 3?

21 A. Yes.

22 Q. So that's, what? \$46,500,
23 roughly, that you've billed -- that you
24 will have billed to date once those

31

1 invoices go out for your work on the TVT
2 general expert report?

3 A. Yes.

4 Q. How much did you --

5 MR. DeGREEFF: Strike that.

6 Q. Did you do any additional report
7 related to the Gynecare mesh products?

8 By that I mean I guess the POP
9 products.

10 A. We have a Gynemesh general
11 report.

12 Q. And was that also done in this

13 litigation for Ethicon?

14 A. Yes.

15 Q. And those were general expert
16 opinions?

17 A. Yes.

18 Q. What did you -- how much have
19 you billed to date for your work on that?

20 A. I don't recall specifically. It
21 was two years ago. It would be in the
22 same ballpark. Maybe just slightly less
23 because it was four products and I think
24 it was a little bit less, but it was in

32

1 the same ballpark.

2 Q. So 40 to \$50,000? Somewhere in
3 there?

4 A. I would say 30 to 50 is the
5 range I could support.

6 Q. Who would know the exact answer
7 to that question?

8 A. I could go back to my bank
9 records. And am certain that whether it's
10 the counsel's office or accounting or

11 Gynecare's accounting, I'm sure they would
12 have it as well. I know I would have it
13 if I reviewed my bank records.

14 Q. When were you first approached
15 to serve as an expert for Ethicon in the
16 transvaginal mesh litigation?

17 A. About three-and-a-half years
18 ago.

19 Q. My math's not very good, but
20 would that be the beginning of 2016?

21 A. Somewhere in the 2016.

22 Q. And you've also done multiple
23 case-specific expert reports on behalf of
24 Ethicon litigation.

33

1 Right?

2 A. Yes.

3 Q. Approximately how much have you
4 billed them for preparing those reports?

5 A. If you put all these together,
6 you put everything together, I think we're
7 probably in the 200 to \$250,000 range. If
8 you put everything you've already, you

9 know, kind of itemized and now tried to
10 expand to the case-specific, say from when
11 I started my relationship with them til
12 now for invoices related to pelvic mesh
13 expert review and participation, it's 200
14 to 250,000.

15 Q. And that is since the beginning
16 of 2016?

17 A. Yes.

18 Q. I just want to make sure I
19 understand what you're saying. I think I
20 do.

21 So, since you were first
22 contacted by Ethicon to serve as an expert
23 in this litigation in early 2016, you've
24 been paid roughly 200 to \$250,000 for your

34

1 work as an expert witness?

2 A. Yes.

3 Q. And that would not include any
4 consulting work you've done for them. It
5 would just be in relation to being a
6 litigation expert?

7 A. This is everything from 2016 and
8 current. Consulting work that I did for
9 Ethicon is more than a decade ago. So
10 this is excluding what was done in the
11 2000 to 2010 was different type of work
12 where I was working with them on product
13 development and all the slings that we
14 discussed.

15 Q. Well, the last time you worked
16 for Ethicon wasn't in 2010.

17 Right?

18 A. I don't recall exactly when. It
19 was probably earlier than that.

20 Q. Well, it was actually later than
21 that.

22 Right?

23 MS. GERSTEL: Object to the
24 form.

35

1 A. As a consultant?

2 I don't recall precisely.

3 Q. As you sit here right now, do
4 you have any understanding of how much you

5 were paid by Ethicon when working for them
6 under a consulting agreement, master
7 consulting agreement, any other such
8 verbiage they used, did you have any idea
9 how much they paid you?

10 A. You know, I don't have an
11 accounting on it on hand.

12 I would estimate in the 20 to
13 35,000 range.

14 Q. Well, in 2011 alone it was over
15 a hundred thousand.

16 Right?

17 MS. GERSTEL: Objection.

18 A. I would have to review that.

19 Q. Okay. We'll get to that.

20 Do you keep any kind of
21 itemization of your item spent on --

22 MR. DeGREEFF: Strike that.

23 Q. So your invoices are broken
24 down, you know, fairly broadly on

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1 Exhibit 3 and 4.

2 Do you have any -- do you submit

3 any kind of a more detailed itemization to
4 Ethicon?

5 A. I don't.

6 Q. Do you have a more detailed
7 itemization?

8 A. The documents that go into
9 making one of those invoices are marked
10 individually. I'll get a binder and I'll
11 go through it and I'll just mark on the
12 front how many hours and then I take those
13 handwritten totals and make a common
14 invoice.

15 Q. Okay. So, is there -- I mean,
16 when you write out your handwritten, do
17 you write out what you did?

18 A. Yeah. I write review of binder.
19 You know, TVT literature, review of
20 literature search on my own, TVT
21 complications. Whatever the category is
22 that I've taken as a meaningful piece of
23 work, I package it and make that a, you
24 know, a time element package that's useful

1 to put a signature on. Or it might be
2 where I have everything I have to look at
3 and I'll go through everything that I have
4 and I'll mark what I've looked at.

5 Q. When you're keeping those notes,
6 do you write down, for example, like if
7 you have a call with defense counsel?

8 A. If I have a what?

9 Q. A call with defense counsel.

10 A. There are some -- there are some
11 invoices that have phone meeting or in
12 person meeting with counsel.

13 Q. Where are those invoices?

14 A. I think those are on some of the
15 case-specific and I think on the -- they
16 may be on the invoice for the Gynemesh. I
17 think it includes one preparatory session
18 that was listed, as I recall. I'm not
19 certain of that.

20 MR. DeGREEFF: Have we -- have
21 those been produced?

22 MS. GERSTEL: At his Gynemesh
23 deposition, we produced invoices. I
24 can't tell you specifically what they

1 were, but I know that we did produce
2 invoices at his Gynemesh deposition.

3 MR. DeGREEFF: Okay. What about
4 the case-specific?

5 MS. GERSTEL: The one
6 case-specific deposition that he's
7 had, it was the Tays deposition in the
8 New Jersey litigation, and we did
9 produce invoices related to his work
10 in the Tays matter at that deposition.

11 MR. DeGREEFF: Okay. Yeah,
12 that's our case.

13 BY MR. DeGREEFF:

14 Q. How many hours would you say --
15 we'll get to this.

16 But how many hours would you say
17 since you started working with Ethicon in
18 2016 that you've spent working as an
19 expert witness for them?

20 MS. GERSTEL: Objection.

21 A. Two hundred thousand divided by
22 five hundred. Whatever it is.

23 I'm also not great at quick

24 math.

39

1 200 to 250,000 divided by 500.

2 So 500 times -- 500.

3 Q. Five hundred hours or so?

4 A. Yeah.

5 Q. I guess 400 to 500?

6 A. Yeah. Yes.

7 Q. And in this litigation --

8 MR. DeGREEFF: Strike that.

9 Q. In preparation of the report
10 we're here about today, which is the TVT
11 general report, based on your Exhibit 3
12 and Exhibit 4, it looks like you spent
13 about 53 hours, plus the 25 that you've
14 spent since then.

15 Is that right?

16 A. What's on those two plus 25.

17 Q. So double check me, but that's,
18 what? 78?

19 A. 21 and 32 is 53 and 25.

20 Yeah, about 78.

21 Q. How much of that 78 hours was

22 spent --

23 MR. DeGREEFF: Strike that.

24 Q. How much of that 78 hours was

40

1 spent in actual drafting and preparation
2 of the report itself?

3 A. One-third.

4 Q. 25 to 30 hours?

5 A. Yes.

6 Q. And the rest of it was spent
7 doing what?

8 A. Research and reading.

9 Q. Did you prepare the reliance
10 list?

11 A. The reliance list has articles
12 provided by counsel, as well as several --
13 many, many that I found on my own, Pub Med
14 searches that I felt were relevant.

15 Q. Who drafted the reliance list?

16 A. Counsel.

17 Q. That's counsel for Ethicon?

18 A. Yes.

19 Q. I guess when I ask that

20 question, to be clear, who drafted the
21 supplemental reliance list?

22 A. I would come up with more
23 articles and would say they're relevant,
24 and then they would be added by counsel

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1 for Ethicon.

2 Q. So counsel for Ethicon drafted
3 the supplemental reliance list?

4 A. Yes.

5 Q. So, the other it's like 45, 50
6 hours --

7 MR. DeGREEFF: Strike that.

8 Q. The other 50 hours or so were
9 spent in review of the materials on the
10 reliance list?

11 A. Finding the materials and
12 reviewing them, yes.

13 Q. Does that 50 hours include any
14 time preparing for your deposition with
15 counsel?

16 A. Yes. We met twice.

17 Q. About how long did you meet each

18 time?

19 A. Four hours.

20 Q. So that's about eight hours

21 total?

22 A. Yes.

23 Q. And when were those meetings?

24 A. Last week and the week before.

42

1 Q. Where were they?

2 A. They both -- one was here. One
3 was in my office.

4 Q. That eight hours was included in
5 the 78 we discussed earlier.

6 Right?

7 A. Yes.

8 Q. So, more like 40 hours probably
9 locating and reviewing the materials in
10 the reliance list?

11 A. Sounds about right.

12 Q. Any phone calls with counsel
13 included in that 78 hours?

14 A. One or two brief, minutes,
15 minutes on each.

16 Q. During your meetings with
17 counsel, were there any specific documents
18 you were shown?

19 A. We went over the -- certainly
20 the two binders here which are the
21 references that relate to my expert
22 report. There were various other -- many,
23 many of the document from the reliance
24 list.

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1 I was shown some company
2 documents.

3 There was -- we reviewed IFUs.

4 Q. So, the binders you referenced
5 are the binders of literature you've got
6 in front of you?

7 A. Yes.

8 Q. What company documents were you
9 shown?

10 A. Testimony by, you know,
11 certainly not comprehensive, by selected
12 administrators in Ethicon and what they
13 had to say about -- in their depositions

14 or what they might have said in developing
15 the products, some extracts of e-mails.

16 Q. So you were shown some
17 deposition testimony?

18 A. Yes.

19 Q. You were shown some e-mail
20 extracts?

21 A. Yes.

22 Q. Anything else?

23 A. No, I don't think so.

24 Q. Who selected the documents you

44

1 were shown?

2 A. You know, I asked for a few
3 things. I had -- I had -- I asked if --
4 you know, what documents, you know, have
5 come under scrutiny in other depositions
6 are the ones that I might want to look at,
7 and counsel had some documents that she
8 recommended I see.

9 Q. So counsel selected some of the
10 documents and you selected some of the
11 documents?

12 A. I said show me -- I said show me
13 the good stuff and show me the bad stuff.

14 Q. And then from there, it was
15 selected by defense counsel?

16 A. It was kind of a combination of
17 things I was curious about and things she
18 thought would be relevant.

19 Q. So, I think the answer to my
20 question is yes. Right? That defense
21 counsel selected some of the documents you
22 were shown?

23 MS. GERSTEL: Object to the
24 form.

45

1 A. No. I think the answer is that
2 I requested to see certain types of
3 documents, and she selected others.

4 Q. That's the same thing.

5 Then there was another category
6 of things you said you reviewed that you
7 were shown.

8 What was it?

9 We had the binders, the internal

10 documents. I believe there was something
11 else you noted.

12 A. There were e-mails, some
13 testimony. Looked at IFUs, which are
14 company documents, a subset of the company
15 documents.

16 Q. What e-mails were you shown?

17 A. There were some members of the
18 development team giving opinions as to
19 whether or not an issue was stiff. There
20 were some e-mails talking about whether a
21 certain design of a sling might cause
22 pain, should we be designing it that way.
23 It was a -- certainly a small subset of
24 review as I was told the size of the

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1 company documents that existed and the
2 testimonies that were weeks long. So it
3 certainly was not comprehensive.

4 Q. These were e-mails and documents
5 by Ethicon employees?

6 A. Yes.

7 Q. And what did the Ethicon

8 employees have to say about the stiffness
9 of the mesh?

10 MS. GERSTEL: Object to the
11 form.

12 A. There was concern of differences
13 between machine-cut mesh and laser-cut
14 mesh and if laser cut mesh was stiffer,
15 might it be an issue in planning for the
16 products it was planned for use in.

17 Q. So, the Ethicon employees in the
18 materials you reviewed were concerned
19 about laser cut mesh being stiffer?

20 MS. GERSTEL: Object to the
21 form.

22 A. It was expressed as one of the
23 concerns.

24 Q. And why were they concerned

47

1 about the stiffness of mesh?

2 A. You know, there was conjecture
3 that if it was stiffer, it might behave
4 differently in clinical performance.

5 Q. So, your understanding of the

6 e-mails you reviewed from the Ethicon
7 employees was that they were concerned
8 that stiffer mesh would lead to more
9 complications.

10 Is that true?

11 A. I don't recall that wording.

12 I do recall them discussing
13 whether it would have relevance to
14 outcome, which of course would include
15 efficacy and safety, but I don't recall
16 specific wording that it would increase or
17 decrease complications.

18 Q. So they were concerned about
19 whether there would be nor negative
20 outcomes with laser cut mesh because it
21 was stiffer?

22 MS. GERSTEL: Object to the
23 form.

24 BY MR. DeGREEFF:

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1 Q. Is that your understanding?

2 A. I'm going to stick to my answer
3 that they were concerned about whether it

4 would change efficacy and safety. Safety
5 would, of course, include any changes in
6 positive or negative outcomes.

7 Q. Well, I mean, someone wouldn't
8 be concerned about a positive outcome?

9 Right?

10 MS. GERSTEL: Object to the
11 form.

12 A. You know, one of the things that
13 I think is important to share is that when
14 these e-mails are shared, it's an
15 extracted e-mail from a sequence of
16 discussions.

17 Q. Sir, that's not the question
18 that's pending. We'll read my question
19 back.

20 (The requested portion of the
21 record was read by the Court Reporter.)

22 A. I think they would be concerned
23 about a change that might be positive for
24 the mesh as well as negative for the mesh.

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1 Q. Okay. So, your understanding

2 from those e-mails, just to make sure I
3 understand what you're saying, is that the
4 Ethicon employees were concerned about the
5 efficacy and safety outcomes related to
6 stiffness of mesh.

7 A. Yes.

8 Q. And then you said that you
9 reviewed some e-mails from Ethicon
10 employees related to whether a certain
11 design -- related to certain designs of
12 mesh.

13 Is that correct?

14 A. Yes.

15 Q. When we're talking about
16 laser-cut mesh, some of the TVT products
17 we're here about today are laser-cut mesh.

18 Correct?

19 A. Yes.

20 Q. Which of the TVT sling products
21 use laser-cut mesh?

22 A. The TVT-Exact and the Abbrevio
23 are all laser-cut. The other two are
24 laser cut, mechanically-cut. Some of it's

1 geographic distribution and some of it's
2 physician request.

3 Q. So the TVT and the TVT-0 have
4 both laser and mechanic-cut options?

5 A. Yes.

6 Q. So, the e-mails that you were
7 reviewing related to the Ethicon employees
8 discussing design of a product, can you
9 tell me what your understanding was of
10 those e-mails?

11 A. When the obturator, the TVT-0
12 was being designed and developed, the
13 questions, and there were e-mails
14 discussing whether the passage -- the
15 difference in passage would affect, you
16 know, the leg or the groin. I do recall
17 some discussions on that.

18 Q. Okay. So, the -- your
19 understanding was that the Ethicon
20 employees were discussing whether the
21 transobturator approach would lead to
22 increased groin pain.

23 Is that true?

24 MS. GERSTEL: Object to the

1 form.

2 A. I think that was one of the
3 concerns expressed in the e-mails, yes.

4 Q. What other concerns were
5 expressed in the e-mails?

6 MS. GERSTEL: Object to the
7 form.

8 A. I don't recall others that are
9 coming to mind presently.

10 Q. And the transobturator approach
11 is used by the TVT-0 and TVT-Abbrevio.

12 Correct?

13 A. Correct.

14 Q. Are you aware of literature
15 concerning potential increased risks
16 associated with the transobturator
17 approach versus the retropubic?

18 MS. GERSTEL: Object to the
19 form.

20 A. Yes.

21 Q. And what does that literature
22 say? What are the potential increased

23 problems?

24 MS. GERSTEL: Object to form.

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1 A. The TVT-0 has a higher increase
2 in groin pain, which is usually transient.
3 It has a higher increase in vaginal angle
4 perforations the it has a less incidence
5 in bladder injury and retropubic injuries.

6 Q. Is there a -- are you aware of
7 literature saying that there's a two times
8 greater risk of re-operation with
9 transobturator placement versus
10 retropubic?

11 MS. GERSTEL: Object to form.

12 A. You know, the articles that
13 describe increased risk of operation need
14 to be looked at individually because I'm
15 aware -- the answer to your question is
16 yes, but I can't confirm that being a
17 legitimate statement because I have to
18 look at the details of the article because
19 they're very specific as to why they were
20 re-operated on and the data is mixed.

21 There is not consensus data or data at a
22 high level that suggests that the
23 re-operation rate is two times greater
24 with obturator, but there are reports.

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1 Q. So you are aware of the
2 literature stating that?

3 A. Yes.

4 Q. And is that literature contained
5 in your reliance list?

6 A. There's a hell of lot of TVT-0
7 literature in my reliance list. So I
8 believe a lot of it is there, yes .

9 Q. The e-mails we just discussed by
10 the Ethicon employees with regard to the
11 laser-cut mesh or the transobturator
12 placement, are those on your reliance
13 list?

14 MS. GERSTEL: Object to form.

15 A. I'm trying to think if I have
16 some. Let me just check.

17 (Pause.)

18 There are a number on the

19 reliance list, yes.

20 Q. The internal e-mails we just
21 talked about discussed within -- with
22 Ethicon employees discussing laser-cut
23 mesh and the transobturator approach,
24 those are included on your reliance list?

54

1 A. I'm not aware of that. No, I
2 don't think so.

3 Q. Did you see those documents for
4 the first time in preparation for this
5 deposition?

6 A. I don't -- I think I may have
7 seen them prior to the TVT Retropublic
8 deposition.

9 MS. GERSTEL: Dave, could I
10 state for the record that as the
11 reliance list was prepared by counsel,
12 I believe those e-mails are on Dr.
13 Lind's reliance list.

14 MR. DeGREEFF: I think you can
15 probably take him through that stuff,
16 if you want. And you're welcome to

17 state whatever you want for the
18 record, obviously. But I'm interested
19 in what he knows.

20 MS. GERSTEL: Okay. I just
21 wanted to make clear that the company
22 documents that were provided to Dr.
23 Lind were put on his reliance list.

24 MR. DeGREEFF: Gotcha.

55

1 BY MR. DeGREEFF:

2 Q. So, the first time you looked at
3 the e-mails we're discussing now was in
4 preparation for your prior deposition on
5 the TVT and the Gynecare?

6 A. Yes.

7 Q. So the first time you saw those
8 was after you had already rendered your
9 opinions?

10 A. I don't recall if it was before
11 or after.

12 Q. Do you recall seeing them before
13 you gave your opinions?

14 A. I don't recall.

15 Q. Something you considered when
16 you were giving your opinions?

17 MS. GERSTEL: Object to form.

18 A. If I had read them, then I
19 considered it. And if I didn't, then I
20 didn't. And I don't remember if I saw
21 them before or after.

22 Q. You said you also reviewed some
23 depositions in preparation for this
24 deposition.

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1 Do you remember what depositions
2 you reviewed?

3 A. I don't remember specifically
4 which one it was.

5 Q. Do you remember the subject
6 matter?

7 A. I just asked to see a deposition
8 that was on the multiple TVT products.

9 Q. Did you review that deposition
10 in preparation for today?

11 A. Yes.

12 Q. When did you review it?

13 A. Three weeks ago.

14 Q. And you don't remember who the
15 person being deposed in that deposition
16 was?

17 A. I don't.

18 Q. What about the TVT products were
19 you interested in from that deposition?

20 A. I was interested in knowing what
21 another expert did in discussing the
22 products. I was interested in what
23 counsel was interested in focusing on.

24 Q. So, was it another deposition

57

1 taken by my firm?

2 A. I believe it was.

3 Q. Do you know who took the
4 deposition?

5 A. Yes. It was Jeff Kuntz.

6 Q. Jeff Kuntz (different
7 pronunciation)?

8 A. Kuntz.

9 I'm sorry if I mispronounced it.

10 Q. What in particular was it --

11 MR. DeGREEFF: Strike that.

12 Q. Why did you need to see how
13 another expert --

14 MR. DeGREEFF: Strike that.

15 Q. Was it a plaintiff's expert or a
16 defense expert? I assume it was a defense
17 expert since we were taking it.

18 A. Yes.

19 Q. Why did you need to see how
20 another Ethicon expert responded to the
21 questions they were being asked?

22 MS. GERSTEL: Object to the
23 form.

24 A. It's someone going through what

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1 I was going to go through. It seemed like
2 a reasonable review method to hear what
3 counsel had to see and take a look at what
4 counsels had to say and see if I agreed
5 with what the other person said, if I
6 would have answered it differently.

7 Q. I mean, isn't the most important
8 thing just for you to answer the questions

9 honestly?

10 MS. GERSTEL: Object to form.

11 A. Well, I think the importance is
12 for me to get prepared in the best way I
13 can to have the knowledge and at the same
14 time answer honestly.

15 Q. So, the best way for you to get
16 prepared to have the knowledge for this
17 deposition was to read what another
18 Ethicon defense expert who was being paid
19 by Ethicon said in his deposition or her
20 deposition?

21 MS. GERSTEL: Object to the
22 form.

23 A. The best preparation was review
24 of the literature, which constituted 99

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1 percent of my time spent. So this was a
2 small element.

3 Q. Is this the only deposition you
4 reviewed in getting ready for your depo?

5 A. Yes.

6 Q. What about expert reports, did

7 you review any expert reports in preparing
8 for your depo?

9 A. I did not.

10 Q. Before we move on, let me ask
11 this question.

12 With regard to the e-mails that
13 we discussed where the Ethicon employees
14 were discussing outcomes related to laser
15 cut mesh.

16 Do you agree or disagree with
17 those employees?

18 MS. GERSTEL: Object to form.

19 A. I don't know the full context of
20 where the e-mails were, and I don't know
21 if they were in the middle of discussions
22 of positives or negatives 'cause they're
23 single pages. So I really can't comment
24 on them.

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1 Q. So you weren't shown the full
2 document?

3 MS. GERSTEL: Object to form.

4 A. I wasn't shown the full thread

5 of e-mails. They were just extracted
6 pages.

7 Q. Who extracted the pages?

8 MS. GERSTEL: Object to form.

9 A. I don't know what was available
10 to Ethicon and to counsel and whether I
11 got everything that they had or whether
12 some of it was extracted.

13 Q. But the documents you were
14 provided by defense counsel to review were
15 incomplete and did not contain the rest of
16 the thread.

17 True?

18 MS. GERSTEL: Objection.

19 A. Some of them did and some of
20 them did not.

21 MS. GERSTEL: Would it be a good
22 time for a break? Or in the next few
23 minutes.

24 MR. DeGREEFF: Sure. This

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1 works. Whatever.

2 (Recess taken.)

3 (Lind Exhibit 6, Curriculum
4 Vitae of Dr. Lind, was marked for
5 identification, as of this date.)

6 BY MR. DeGREEFF:

7 Q. I've just handed you what I've
8 marked as Deposition Exhibit Number 6.

9 Do you recognize that as your
10 current CV?

11 A. Yes.

12 Q. Sir, what kind of doctor are
13 you?

14 A. I'm an obstetrician gynecologist
15 with fellowship training in female pelvic
16 medicine and reconstructive surgery.

17 Q. Do you have any board
18 certifications?

19 A. I'm board certified in OB-GYN
20 and I'm subspecialty certified in female
21 pelvic medicine and reconstructive
22 surgery.

23 Q. What states are you licensed to
24 practice medicine in?

1 A. Just New York.

2 Q. Sir, if you look at there's a
3 portion that says teaching experience?

4 A. Yes.

5 Q. In the teaching experience
6 section of your CV, are any of the things
7 listed there done on behalf of Ethicon?

8 A. The last one, the 2006 to
9 present, the bio skills training labs, we
10 set those up to teach our fellows, and
11 there's usually an educational grant
12 offered by each of the major companies
13 that supply pelvic floor products that
14 usually pick up the cost for the lab. So
15 some of those are supported. They
16 probably would have been between 2006 and
17 2010, some labs that were supported by
18 Ethicon.

19 The rest of them are mostly
20 academic courses that were at a facility
21 and supported by the facility.

22 Q. Okay.

23 So, would Ethicon have -- when
24 you say "supported," you mean paid for.

1 Right?

2 A. They cover the cost of the lab,
3 the cadaver lab for the day. We would not
4 be getting paid for that lab, but they're
5 picking up the expense of cost to use
6 cadavers to teach.

7 Q. What is the cost to use cadavers
8 to teach?

9 A. A lab could be \$30,000.

10 Q. Each lab?

11 A. Yeah. The cost for the cadavers
12 and the people who prepare them, maintain
13 them and dispose of them is very high.

14 Q. And Ethicon would pick up one of
15 the --

16 MR. DeGREEFF: Strike that.

17 Q. How many of those cadaver labs
18 per year would Ethicon pick up?

19 MS. GERSTEL: Objection.

20 A. They probably do one a year in
21 the general teaching sense.

22 Q. For four years or so, is what
23 you're saying?

24 I guess how many years did they

64

1 do that?

2 A. Yeah, four to six years. And
3 the other companies would do the same. We
4 have a lot of teaching labs. So Boston
5 Scientific would pick up a lab. Caldera
6 would pick up a lab.

7 Q. Okay.

8 So, I mean, Ethicon would have
9 spent 120 to \$180,000 on cadaver labs --

10 A. Yeah.

11 Q. -- based on what we just talked
12 about.

13 Is that correct?

14 A. Yes.

15 But I would like to specify that
16 it was the hospital rules and compliance
17 that they would have to have absolutely no
18 input as to the material, slides, things
19 taught, and the products are not
20 exclusively theirs. They were everything
21 that we think the students and fellows

22 need to learn.

23 MR. DeGREEFF: I'm going to move
24 to strike that, and I'm going to ask

65

1 my question again.

2 BY MR. DeGREEFF:

3 Q. My question was pretty simple.

4 It was just a yes or no.

5 Ethicon would have spent 120 to
6 \$180,000 on cadaver labs based on our
7 discussion.

8 True?

9 MS. GERSTEL: Object to form.

10 A. Across those several years, yes.

11 Q. There's also a list of lectures.
12 I guess the title is lecture
13 presentations, on your CV.

14 Do you see that?

15 A. Yes.

16 MR. DeGREEFF: Strike that.

17 Before I do that, let me go back.

18 BY MR. DeGREEFF:

19 Q. Who was teaching these cadaver

20 labs that were funded by Ethicon?

21 A. My division, which would be
22 myself and my partners.

23 Q. Would Ethicon fund these cadaver
24 labs at the request of you and your

66

1 department?

2 A. Yes.

3 Q. Now are the lecture presentation
4 section of your CV.

5 Do you see where I'm at?

6 A. Yes.

7 Q. Were some of those lectures done
8 on behalf of Ethicon?

9 A. The ones listed here are all
10 invited lectures in academic only
11 situations and not for Ethicon.

12 I don't have listed here invited
13 Ethicon lab experiences where I taught at
14 their Ethicon teaching experiences.

15 Q. Does the lecture presentation
16 section include lectures given on behalf
17 of any transvaginal mesh manufacturer?

18 A. No.

19 Q. Why did you not include in your
20 lecture presentation section those that
21 were done on behalf of transvaginal mesh
22 manufacturers?

23 A. I guess when I'm writing an
24 academic CV, I'm thinking about my

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1 academic presentations. And those were in
2 a consultant role, so I didn't include
3 them.

4 Q. What is the difference between
5 the lectures you gave in a consulting role
6 versus those given in an academic setting.

7 A. These were advised by me or
8 offered to institutions for teaching
9 purposes only or invited because of my
10 expertise to give teaching, and the others
11 were labs we set up to teach, for which we
12 couldn't have the setting of fresh
13 cadavers without the backing of companies
14 because we didn't have the money for the
15 labs and it was a unique teaching

16 situation.

17 It was really access to the
18 cadavers was the key teaching element. So
19 it was more of a -- it was less of a
20 lecture than the opportunity to execute
21 procedures in a unique way that had really
22 not been done before to be able to do them
23 on fresh cadavers.

24 Q. Well, when you're giving

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1 lectures as a consultant for Ethicon, you
2 were being paid, right?

3 A. Well, let me make a distinction.

4 The labs that we're talking
5 about where I'm teaching at my lab center,
6 I'm lecturing on whatever I want for
7 pelvic reconstructive surgery on various
8 procedures. Some of the procedures have
9 nothing to do with mesh or any product and
10 others do.

11 And in the discussions of mesh
12 products, there is not any selection for
13 that lab when Ethicon's paid for it that

14 discusses theirs only. It's we describe
15 everything we use for the reasons we use
16 them. So we presented it in a non-biased
17 way.

18 Q. What you just gave the
19 explanation about, that's what you're
20 referring to in the academic setting,
21 right?

22 A. The academic setting in my lab.
23 Now, the distinction that will also put it
24 into a teaching category is when Ethicon

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1 wanted to teach the procedures, each of
2 these slings or the mesh procedures and
3 they wanted expert surgeons to help train
4 people on fresh cadavers. At that would
5 be a different teaching setting which I
6 would say is teaching-slash-consulting.

7 Q. Right.

8 When you're giving lectures as a
9 consultant, you're being paid by Ethicon
10 pursuant to the consulting agreements you
11 signed with them.

12 Right?

13 A. Yes.

14 Q. And they have input into the
15 materials you're using for those lectures.

16 True?

17 A. I did not permit that.

18 Q. Well, contractually under
19 consulting agreement, they have the right
20 to have input into those materials,
21 correct?

22 MS. GERSTEL: Object to the
23 form.

24 A. They could have input, but I

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1 control the slides.

2 I would never accept a company's
3 slide deck, and I never did.

4 Q. Those two things, i.e. being
5 paid and -- being paid by Ethicon and
6 Ethicon's right to review and have input
7 in your materials, those aren't present in
8 the academic setting.

9 Right?

10 A. Correct.

11 Q. You have a bibliography section
12 on your CV. I'm sure you're aware of
13 that.

14 Right?

15 A. Yes.

16 Q. Have you published any
17 peer-reviewed articles regarding any of
18 the Ethicon mesh slings?

19 A. No.

20 Q. Have you published any
21 peer-reviewed articles concerning mesh
22 slings regardless of the manufacturer?

23 A. We contributed cases to a Solyx
24 study, which was published.

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1 Q. Was it peer-reviewed?

2 A. Yes.

3 Q. And were you the author or did
4 you just contribute in some other way to
5 that?

6 A. I was a co-author. I was not
7 the lead author.

8 Q. And which one was the -- on your
9 bibliography was that particular article?

10 A. On the second page, it says
11 Nosseir S, Serels and Lind Safety and
12 efficacy of the Solyx single-incision
13 sling.

14 And then we had another -- we
15 had a posterior presentation, which is
16 peer-reviewed for acceptance as a poster,
17 but it's not a -- published in a journal a
18 little further down by the same group.

19 Q. And those were both with regard
20 to the Solyx?

21 A. Yes.

22 Q. Any others? Any other
23 peer-reviewed articles related to mesh
24 slings that you published?

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1 A. We did on the third page. You
2 can see the first name Shalom where it
3 says "Visualization of synthetic mesh
4 utilizing optical coherence tomography.
5 That wasn't efficacy or complications of

6 mesh, but it was -- what we thought we
7 were trying to do there was, you know,
8 special optical tomography device that
9 would let us find the sling and we thought
10 it might be useful for it when you have to
11 go back and note a little more precisely
12 where the sling is.

13 Q. So that would be useful for when
14 people were having complications and you
15 needed to look at the sling?

16 A. Yes.

17 Q. Were these two Boston Scientific
18 articles that you discussed that were
19 peer-reviewed, were they funded by Boston
20 Scientific?

21 A. They were.

22 Q. They were?

23 A. Yes.

24 Q. Do you remember how much you

73

1 were paid for your work on those?

2 A. I do not, but I do -- I can
3 clarify that the funds would go to a

4 research fund and in no way would
5 remunerate me financially.

6 Q. Was there any other of your
7 articles in your bibliography that were
8 funded by transvaginal mesh manufacturers?

9 A. On the second page it has
10 Cholhan and Lind, the "Prepubic Approach
11 to Mid-Urethral Slings." That was funded
12 by Boston Scientific.

13 Q. Okay.

14 A. I'm scanning the rest of them.

15 (Pause.)

16 No others.

17 Q. On the articles that you worked
18 on that were funded by transvaginal mesh
19 companies, did you do a disclosure of
20 conflict of interest?

21 A. Yes.

22 Q. What is the purpose of
23 disclosing that an article was funded by a
24 mesh manufacturer?

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1 A. Well, both at the point of

2 patient consent and at the point of
3 publication, the disclosure allows the
4 readers to understand that there was a
5 financial support by a company that has
6 relevance for the result of the study. A
7 reader can decide whether that financial
8 disclosure introduces bias and judge that
9 as to whether or not to credit the study
10 more or less based on that.

11 Q. When someone receives funding or
12 payment from an entity, there's potential
13 bias that can result.

14 True?

15 A. There's the potential, yes.

16 Q. How do you define bias?

17 A. Bias is when a -- in the setting
18 of a study, when you're interpreting a
19 study or how you're handling your patients
20 or how you're looking at results, you have
21 a feeling or an impetus to want it to go
22 in one direction or another that may not
23 be objective. That's if you're not
24 handling it properly.

1 So, if you had bias and you were
2 not able to resist bias in a study, you
3 would be influencing the study in one way
4 or another because there was financial
5 support.

6 Q. I think you put it very well in
7 another deposition I saw that you gave.
8 Bias is -- would you agree that bias is
9 anything that affects the objectivity of
10 the outcome of a study?

11 A. Sure. That's one way of looking
12 at it.

13 Q. One of the things that could
14 affect the objectivity of a study is
15 funding or payment.

16 True?

17 A. It could, but there are defenses
18 against that.

19 Q. Which, if any, of the articles
20 on your bibliography are relevant to the
21 TVT sling products?

22 MS. GERSTEL: Object to form.

23 A. Well, I think I've got a lot
24 of --

1 MR. DeGREEFF: Strike that. Let
2 me ask that in a more fairway. That
3 was a pretty broad question.

4 BY MR. DeGREEFF:

5 Q. Do any of the articles in your
6 bibliography relate to or address any of
7 the TVT products?

8 A. I think they're not directly
9 studies on TVT products, but I think
10 they're products on -- they're studies on
11 incontinence procedures which are relevant
12 to how TVT fits into the incontinence
13 surgery products history.

14 I have a number of mesh studies
15 which are relevant to procedures with
16 mesh, whether they're prolapse procedures
17 or incontinence.

18 Q. Well, the TVT products are not
19 for prolapse.

20 Correct?

21 A. Correct. I was indicating that
22 the behavior of the same type of mesh

23 would be relevant to, in a broader scope,
24 how mesh behaves.

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1 Q. I think you answered this, but
2 let me just confirm because you said it in
3 a better way than I did.

4 None of the articles included on
5 the bibliography are on the TVT -- any of
6 the TVT sling products.

7 Correct?

8 A. Correct.

9 Q. So you have not been direct --
10 you have not been involved directly in a
11 published study of any kind related to
12 the, or about the TVT products?

13 A. Correct.

14 Q. What are some alternatives to
15 slings?

16 MS. GERSTEL: Object to form.

17 A. There are, historically, there
18 are dozens and dozens of stress
19 incontinence procedures. They include
20 Burch, needle procedure, Pereyra, Stamey,

21 pubovaginal slings, amongst others.

22 Q. Which of the native sling --

23 MR. DeGREEFF: Strike that.

24 Q. Which of the alternatives to

78

1 mesh slings are still in use today?

2 A. The pubovaginal slings are still
3 in use. The Burch is still in use, but to
4 a much lesser degree, markedly lesser
5 degree than previously.

6 Q. Biologic slings?

7 A. They are used by a small number
8 of users. They're certainly not a
9 dominant. But in answer to your strict
10 question, yes, those are still in use.

11 Q. And those alternatives are used
12 for the same indications as the TVT mesh
13 slings.

14 True?

15 A. Yes.

16 Q. Have you ever performed the
17 Burch procedure?

18 A. Many, many times.

19 Q. Do you still perform it?

20 A. Yes.

21 Q. How many times have you
22 performed it?

23 A. In my career, 300, 400.

24 Q. When was the last time you did

79

1 one?

2 A. Within the last few months.

3 Q. How many have you done this
4 year? Any idea?

5 A. Three or four.

6 Q. What about have you ever done
7 the native tissue sling procedure?

8 A. Yes.

9 Q. Do you still do it?

10 A. I do.

11 Q. How many have you done?

12 A. I did two this year.

13 Q. How many have you done in your
14 career?

15 A. 50 to 60.

16 Q. What about the biologic slings,

17 have you ever used one of those?

18 A. I did not.

19 Q. The Burch procedure and the
20 native tissue repair are still viable
21 alternatives to the TVT mesh slings that
22 are still being used.

23 Right?

24 MS. GERSTEL: Object to form.

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1 A. Can you just restate that?

2 Q. The Burch and native tissue
3 slings are still available alternatives
4 that are still in use to the TVT slings.

5 Fair?

6 A. Yes.

7 Q. Sir, are you involved in any
8 current research on polypropylene meshes?

9 A. We have a -- I'm not a co-author
10 on it, but we have in our division, we
11 have some rabbits being implanted with
12 absorb -- partially absorbable and
13 absorbable mesh to analyze the biochemical
14 and histochemical changes during

15 implantation.

16 Q. Are you involved in that at all?

17 A. I'm involved in the chat in our
18 research sessions. They're not my
19 project. I'm not the mentor or co-author
20 on them. But since it's in the division,
21 every Friday we go over products. So I'm
22 privy to the updates and the ongoing
23 happenings on it, but I have no ownership
24 on that project.

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1 Q. So you're not -- you've had some
2 conversations about the project, but
3 you're not involved in actually
4 administering the project.

5 Fair?

6 A. Correct.

7 Q. Is that project being funded by
8 a pharmaceutical company -- or, excuse me.
9 A medical device company?

10 A. It is. It's being funded by a
11 mesh company.

12 Q. Which one?

13 A. I don't know the name.

14 Again, I'm kind of peripheral on
15 this one.

16 Q. Okay.

17 Is it Ethicon?

18 A. It's small. It's not one of the
19 well-known companies.

20 Q. Have you ever written a
21 peer-reviewed journal article on
22 polypropylene mesh?

23 A. Yes. I have a publication on
24 the reduction of the analysis of mesh

82

1 complications with abdominal sacral
2 suspension done in different ways for
3 abdominal sacral suspension analyzing
4 erosion rates.

5 Q. What product was at issue?

6 A. Gynemesh.

7 Q. Not the TVT products?

8 A. No.

9 Q. Have you ever written on the
10 Burch procedure?

11 A. Yes. I have a couple of
12 publications in my CV.

13 Q. Were those peer-reviewed?

14 A. Yes.

15 Q. What was it, do you remember the
16 subject matters you were writing about?

17 A. The Burch procedure requires a
18 fairly good size incision, and I was
19 instrumental in designing a device that
20 would allow suturing in a very small
21 space. So once the device was approved, I
22 wrote a paper on about 90 patients to see
23 whether a Burch could be achieved in a
24 much smaller incision because with the use

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1 of the suturing device, it would
2 facilitate the suturing without needing as
3 much space for visualization. So the goal
4 was to see if I could take a Burch and
5 make it less invasive with an incision
6 that was less than half the size.

7 Q. And what were the results?

8 A. They were excellent. We

9 achieved it.

10 Q. So you came up with a way to
11 make the Burch a less invasive procedure?

12 A. Yes.

13 Q. Do you have a patent on that
14 product?

15 A. I do not.

16 Q. It feels like there's more to
17 that story.

18 Does someone have a patent on
19 it?

20 A. I -- the rules for -- someone
21 has a patent on it and I was offered part
22 ownership to it. My academic affiliation
23 and the roles for ownership of
24 intellectual property were such that

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1 taking the intellectual property would be
2 a poor financial decision.

3 Q. Gotcha.

4 A. So I just came on as a
5 consultant and continued to help them
6 develop the device.

7 Q. Which medical device company was
8 developing it?

9 A. It was the Laurus Corporation,
10 L-A-U-R-U-S. And we developed it with
11 them and they patented it and I did a lot
12 of -- most of the studies to show how it
13 would work and the efficacy and safety.
14 And I wish I had a part ownership because
15 they sold it to Boston Scientific for a
16 nice penny.

17 Q. So, is that device currently in
18 use today?

19 A. Yes, it is.

20 Q. And when did that device get
21 developed?

22 A. I was working on it from '94 to
23 '96 and I think it got sold to Boston
24 Scientific in '96.

85

1 Q. And the end result was that the
2 Burch procedure, which was an alternative
3 to the TVT mesh slings, became less
4 invasive.

5 True?

6 A. That, as well as a few vaginal
7 procedures that we also had trouble
8 suturing with. It had more than one
9 application in addition to the Burch.

10 Q. Were all three of those articles
11 related to that same issue?

12 A. I think there were two on the in
13 line suturing device. Yes, they were on
14 the issue of -- did I do sacrospinous? I
15 think one might have been Burch and one
16 might have been sacrospinous suspension.
17 I can check on that, if it matters.

18 Q. Yes. I think you said three.
19 That's why I was asking.

20 (Pause.)

21 A. There's two. One looked at it
22 for the use in sacrospinous suspension.
23 The other one looked at it for the use in
24 Burch.

86

1 Q. Okay.

2 And what were the findings on

3 the sacrospinous suspension?

4 A. The procedure was able to be
5 performed with less dissection and in less
6 operative time with good efficacy and
7 minimal to no complications. So it didn't
8 add any adverse effects and it lessened
9 the dissection and operative time.

10 Q. And is that also a -- is that
11 procedure also a sling alternative?

12 A. No. That's for pelvic prolapse.
13 That's for vaginal apex prolapse.

14 Q. Have you ever written anything
15 on the biologic tissue slings?

16 A. I have not.

17 Q. Do you consider yourself an
18 expert on chemical engineering?

19 A. As it relates to slings, yes.

20 Q. And what is the basis? Why are
21 you an expert in chemical engineering?

22 A. Because the issues related to
23 chemical engineering as it pertains to
24 tissue interaction with mesh and implants

1 has been part of my career studying,
2 implanting, taking care of patients,
3 insuring their safety and observing the
4 behavior. So that's 25 years of
5 experience.

6 Q. Do you have any education in
7 chemical engineering?

8 A. I read quite a bit of literature
9 on the behavior of the mesh and how it
10 interacts with tissue. So my education is
11 based on independent review of the
12 literature, and I do not have a Ph.D.

13 Q. Well, I think we're talking
14 about two different things.

15 Are you talking about
16 biomaterials right now versus chemical
17 engineering? True?

18 A. Whether it's chemical
19 engineering or biomaterials, how they
20 relate to the behavior of slings implanted
21 in patients, I consider myself an expert.

22 Q. You don't know anything about
23 the chemical engineering of polypropylene
24 mesh itself.

1 True?

2 A. I would say that's false.

3 Q. Okay. Why is it false?

4 A. Because I've read articles about
5 the process of it coming from resin, how
6 it gets transformed from resin, and how it
7 gets made into fibrils and how it gets
8 made into the decision to how the fibrils
9 get made and the width of the fibrils. So
10 I've done reading on how they take it from
11 powder and resin and transformed into
12 materials and the reasons why they make
13 decisions.

14 Q. So, is it your testimony that
15 reading articles about how they make
16 transvaginal -- excuse me. Polypropylene
17 mesh is why you consider yourself a
18 chemical engineering expert?

19 A. Reading articles, seeing the
20 different outcomes of how the chemical
21 engineering goes into making products
22 different and seeing how it behaviors in
23 patients and seeing the outcomes for 25

24 years is my basis for stating I'm an

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1 expert on that topic as it relates to mesh
2 in sling behavior.

3 Q. And you've seen all of that in
4 your role as a physician.

5 True?

6 A. Yes.

7 Q. No one's ever hired you to be a
8 chemical engineering expert.

9 Right?

10 A. No.

11 Q. No one's ever hired you as a
12 chemical engineer.

13 Right?

14 A. Correct.

15 Q. When you hang your degree on the
16 wall, it doesn't say chemical engineer.

17 Right?

18 A. It does not.

19 Q. Do you consider yourself an
20 expert in pathology?

21 A. As it relates to the behavior of

22 sling and mesh implanted in patients, yes.

23 Q. In your daily practice, what is
24 it that makes you a pathology expert?

90

1 A. The rabbit studies that we're
2 doing produce pathology slides which we
3 examine for various histochemical
4 properties, tensile strength and
5 mechanical properties, and this is a
6 routine part of the research that our
7 group does.

8 Q. You mean the rabbit studies that
9 the other people in your group are doing.

10 Is that what we're talking
11 about?

12 A. To distinguish though what the
13 other people are doing is I play a role in
14 responding and advising what would be
15 studied, how they're doing the study,
16 response on whether how they're getting
17 the information is correct, whether the
18 staining processes are correct. So I'm
19 involved in the study more than just

20 listening.

21 Q. You're not an author on that
22 study.

23 Right?

24 A. I am not.

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1 Q. You are not a co-author on that
2 study.

3 Right?

4 A. I'm an advisor on that study,
5 and I'm part of the education discussions
6 on the process.

7 Q. You are not administering the
8 study.

9 Right?

10 A. No.

11 Q. I'm correct you're not
12 administering the study.

13 Right?

14 A. Correct.

15 Q. You don't even know who the
16 pharmaceutical company is that's funding
17 the study.

18 Fair?

19 A. That's correct.

20 MS. GERSTEL: Object to form.

21 BY MR. DeGREEFF:

22 Q. Other than that, the rabbit
23 studies, what qualifies you as an expert
24 in pathology based on your daily practice?

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1 A. When I review the literature,
2 I'm aware of many articles about excision
3 of specimens, what they look like, how
4 people's opinions and how the pathology's
5 been studied on excised specimens, is
6 there inflammation, is there ingrowth, is
7 there degradation. So I'm very
8 well-versed on the literature related to
9 pathologic specimens of mesh and sling
10 material.

11 Q. Do you actually read the
12 histopathologic slides?

13 A. In the studies that we do, I
14 look at the pictures along with our study
15 group, yes.

16 Q. You're talking about the rabbit
17 thing again.

18 Right?

19 A. Yes.

20 Q. Do you actually review
21 histopathologic slides out of humans as
22 part of your practice?

23 A. I do not.

24 Q. You just read the reports that

93

1 come to you from the pathologists.

2 Right?

3 A. Correct.

4 Q. Have you read any pathology
5 reports related to excised mesh?

6 A. I think the Clave study is one
7 of the studies that gets into that.

8 Q. I mean in your daily practice.

9 Have you reviewed reports,
10 pathology reports from the pathologists,
11 related to mesh that was removed from --

12 A. Yes.

13 Q. -- patients?

14 A. Yes.

15 Q. When you review those reports,
16 do they discuss inflammation of the
17 tissue?

18 A. Sometimes inflammation is
19 mentioned, yes.

20 Q. Do they discuss scar plating
21 related to the mesh?

22 A. I have not read that on a
23 pathology report.

24 Q. Do they discuss degradation of

94

1 the mesh?

2 A. I have not read that on a
3 pathology report.

4 Q. What is the -- inflammation can
5 lead to pain for a woman.

6 True?

7 A. Yes.

8 Q. And it can lead to chronic pain.
9 Right?

10 A. It can, yes.

11 Q. And mesh leads to tissue --

12 MR. DeGREEFF: Excuse me.

13 Strike that.

14 Q. Mesh can cause tissue
15 inflammation.

16 True?

17 MS. GERSTEL: Object to form.

18 A. It -- I would say the mesh
19 itself doesn't cause inflammation, but it
20 could potentiate inflammation.

21 Q. Mesh itself can cause a foreign
22 body reaction.

23 True?

24 A. Yes.

95

1 Q. And that can lead to
2 inflammation?

3 A. True.

4 Q. Do you consider yourself an
5 expert in polymer chemistry?

6 A. As it relates to mesh and
7 slings, yes.

8 Q. This is amazing. If you come up
9 with a yes for that, we're -- okay.

10 What is your background in
11 polymer chemistry?

12 A. My answers would be the same as
13 I replied previously for my background
14 for --

15 Q. Okay. So, your answer to -- I
16 just want to make sure anything I asked
17 you about chemistry or chemical
18 engineering. Your answer is going to be
19 I've read articles on polypropylene mesh
20 and I listen to updates on the rabbit
21 study.

22 Right? Those are the two
23 things?

24 MS. GERSTEL: Object to form.

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1 A. No. I would expand on that.

2 Q. Okay. What else?

3 A. For 25 years, I've implanted
4 mesh. I've looked at explanted specimens
5 and pathology reports. I have studied the
6 literature. I've read literature both
7 positive and negative, on various

8 engineerings, polymer chemistry and other
9 aspects of scientific ways that you can
10 analyze what happens to mesh. I am
11 participating in a lab that implants mesh,
12 excises mesh, testing it for tensile
13 strength, looking at it under a microscope
14 for various inflammation and histochemical
15 changes and I've been studying this and
16 been participating in educational and
17 clinical and pathology education for 25
18 years.

19 Q. That all makes you a doctor,
20 right?

21 A. No. I'm stating that that makes
22 me an expert.

23 Q. What is your degree in?

24 A. I have an MD.

97

1 Q. Okay. What is your
2 undergraduate degree in?

3 A. I have a bachelor of arts.

4 Q. Do you have any educational
5 training related to chemistry or

6 engineering?

7 A. I have 25 years of additional
8 education as described previously.

9 Q. What you described was 25 years
10 of being a doctor.

11 Right? That's what you're
12 relying on for being a chemist and an
13 engineer?

14 A. That was not my answer.

15 MS. GERSTEL: Object to form.

16 BY MR. DeGREEFF:

17 Q. I'm considering you also
18 consider yourself a biomaterials
19 specialist based on all the stuff we
20 talked about?

21 A. Yes.

22 Q. Any other reasons?

23 A. I think we've gone through them.

24 Q. That's all of them?

98

1 I'm just making sure there's not
2 anything else.

3 A. On biomaterials I think you

4 certainly can say in that area, I have
5 published and tested things on my own,
6 published them and participated in
7 advising and testing in cadaver labs and
8 published materials on my own. So my
9 additional evidence of expertise is
10 stronger in that area.

11 Q. Have you ever published any
12 opinions that polypropylene mesh does not
13 degrade in the human body?

14 MS. GERSTEL: Object to form.

15 A. I haven't published it.

16 Q. Do you consider yourself an FDA
17 expert?

18 MS. GERSTEL: Object to form.

19 A. I'm distinctly aware of FDA
20 matters and paperwork as it relates to
21 mesh products and Ethicon mesh products
22 and the rules that go into IFUs. I would
23 not say I am a comprehensive FDA expert.

24 But I would say as it relates to

1 the matters in this case, I would say I've

2 reviewed the pertinent documents and are
3 comfortably familiar with that.

4 Q. What are the pertinent
5 documents?

6 A. There's a blue book memo and a
7 second FDA document that describes what's
8 required in the release of a product, what
9 has to be on labeling, what has to be
10 included in adverse events, and as it
11 relates to this particular, you know,
12 issue at hand is what adverse events are
13 necessary to be included in an IFU.

14 Q. Because it sounds like you're
15 not claiming you're an FDA expert. You're
16 claiming you're an IFU expert.

17 Right?

18 MS. GERSTEL: Object to form.

19 A. I claim to be an FDA expert as
20 it relates to adverse reactions and the
21 rules necessary and laid out as to what
22 needs to be included.

23 Q. How did you become aware of --

24 MR. DeGREEFF: Strike that.

1 Q. Under what circumstances did you
2 review these FDA materials related to
3 Ethicon products?

4 A. Well, in discussing with counsel
5 became clear that, you know, what warnings
6 are in the IFU is of quick relevant to
7 these cases and I said I'd like to see the
8 FDA documents that dictate the rules.

9 Q. Was that before or after you
10 gave your opinions?

11 A. That was before.

12 Q. So, what you're claiming makes
13 you an expert on the FDA is materials you
14 reviewed in preparing for to be a
15 litigation expert for Ethicon.

16 Is that right?

17 A. Well, if someone were to ask me
18 it I'm an expert in FDA in the broad sense
19 of the word, the general everything that
20 they take care of, I would say no.

21 If I'd say as it pertains to the
22 relevant issues to the materials involved
23 in this case, I would say I have very
24 thoroughly read through the relevant

1 documents and therefore consider myself an
2 expert as it relates to mesh products and
3 adverse warnings and what needs to be
4 included.

5 Q. Did you read the 510(k)
6 submission for this product?

7 A. At some point I did.

8 MS. GERSTEL: Object to form.

9 BY MR. DeGREEFF:

10 Q. Did you read all the testing
11 submitted with the 510(k)?

12 MS. GERSTEL: Objection.

13 A. I don't know if I read all of
14 the testing. I think I was made familiar
15 with some of it.

16 Q. Do you know the difference
17 between clearance and approval of a
18 product?

19 A. There are different pathways to
20 go through the FDA. There's a 510(k)
21 pathway, which is based on a precedent,
22 and then there's another pathway where

23 based on data, it's you go through based
24 on your own merit and data.

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1 Q. What's the other pathway called?

2 A. I don't know.

3 Q. Does 510(k) end up with approval
4 or clearance in the end?

5 A. Approval.

6 Q. Would you be surprised to find
7 out that 515 K ends up with clearance?

8 A. I'm sorry.

9 Q. Would you be surprised to find
10 out that 510(k) ends up with compliance,
11 not approval?

12 MS. GERSTEL: Object to form.

13 A. I may have that vocabulary
14 confused.

15 Q. As a FDA expert, do you think
16 you should probably know the difference
17 between clearance and approval?

18 MS. GERSTEL: Object to form;
19 argumentative.

20 A. I think the key elements here

21 are what the rules are for what needs to
22 be included in an IFU, and I don't think
23 the rules of what the vocabulary term is
24 for approval versus otherwise is the key

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1 element. So no, I wouldn't consider that
2 eliminating myself as an expert to the
3 relevant materials.

4 Q. What I'm taking what you're
5 saying is that you do consider yourself an
6 expert on warnings?

7 A. Yes.

8 Q. What risk information are
9 medical device companies required to put
10 in their IFUs?

11 A. They're required to put in the
12 most common and adverse reactions that are
13 unique to the product, and they are not
14 required to put in things that are
15 commonly known.

16 Q. What industry standards govern
17 warnings in medical devices?

18 MS. GERSTEL: Object to form.

19 A. The FDA.

20 Q. What are the various sections of
21 the regulations that relate to warnings
22 for IFUs?

23 MS. GERSTEL: Object to form.

24 BY MR. DeGREEFF:

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1 Q. And for the record, you're
2 currently look to go your report to give
3 you that answer.

4 Correct?

5 A. That would be correct, because I
6 can't always memorize that it is 21 CFR
7 801.109 (C) and device labeling guidance
8 number G91-1. So at times I may have to
9 refer, since I haven't memorized
10 everything that exists in all of these
11 binders in my report.

12 Q. You think an FDA expert on
13 warnings would know that?

14 MS. GERSTEL: Object to form;
15 argumentative.

16 A. I think an FDA expert on the

17 entirety of the FDA would know that, but
18 that does not exclude me from being an
19 expert on the areas that I previously
20 described.

21 Q. What departments of a medical
22 device company are involved in creating
23 warnings?

24 A. When I have participated on

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1 discussions about what should be included,
2 there's research and development, there
3 was regulatory, and there was compliance.

4 Q. Have you ever read any testimony
5 from Ethicon employees regarding Ethicon's
6 position on what belongs in an IFU?

7 A. I don't recall.

8 Q. Have you ever drafted an IFU for
9 a medical device?

10 A. I didn't draft it.

11 I participated in discussions
12 about what should be included and what
13 shouldn't.

14 Q. What was your participation?

15 A. It was in -- with Boston
16 Scientific in releasing a few of their
17 products.

18 Q. Which products?

19 A. It was the Advantage and then it
20 was their Prolene mesh for sacral
21 suspensions.

22 Q. Did they pay to you do that?

23 A. Yes.

24 Q. How much?

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1 A. Whatever my hourly was then. It
2 was a little lower, \$300 an hour.

3 Q. How many hours did you spend
4 working on that IFU?

5 A. Probably two expert sessions. I
6 would say twelve.

7 Q. Was that like a roundtable
8 discussion about what kind of warnings
9 should be in the IFU?

10 A. Usually was -- it usually was a
11 couple of hours in the lab, then followed
12 up by roundtable discussion.

13 Q. Lab so you could -- was the
14 purpose of the lab to test out the
15 implant, how it worked with the implant of
16 the device?

17 A. Correct.

18 Q. And after you made your
19 recommendations, you didn't have any
20 involvement in the actual drafting of the
21 IFU?

22 A. I did not.

23 Q. Do you agree that physicians
24 should be made aware of the significant

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1 safety risks with a product in the IFU?

2 MS. GERSTEL: Object to form.

3 A. Well, the definition of
4 significant is -- requires a larger
5 discussion than a yes/no question.

6 Q. How do you define significant?

7 MS. GERSTEL: Object to form.

8 A. I would define it as I did
9 before, where they have to describe the
10 most common and unique adverse reactions

11 to the product, but they don't necessarily
12 have to provide -- list adverse reactions
13 that are commonly known.

14 Q. Have you ever read the
15 deposition of Ethicon employee Catherine
16 Beef?

17 A. I have not.

18 Q. Is that something that's on your
19 reliance list?

20 A. I'm not -- I don't recall seeing
21 that. I don't know if it's on the
22 reliance list.

23 Q. If it was her testimony that
24 physicians should be made aware of all

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1 significant safety risks associated with a
2 product in the IFU, is that something you
3 disagree with?

4 MS. GERSTEL: Object to form.

5 A. Yes, I disagree.

6 Q. Do you agree that the
7 manufacturer of a medical device that's
8 going to be implanted in a woman's body is

9 required to disclose all significant risks
10 to doctors that come with the use of the
11 device?

12 MS. GERSTEL: Object to form.

13 A. No.

14 Q. You do not agree?

15 A. I do not agree.

16 Q. Were you ever provided the
17 deposition of Ethicon's medical director
18 Dr. Weissberg?

19 A. I don't recall it.

20 Q. If the medical director
21 testified that that's the case, do you
22 disagree with Ethicon's medical director?

23 MS. GERSTEL: Object to form.

24 A. Yes.

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1 Q. The warnings and adverse
2 reactions section should include all
3 significant risks and complications
4 related to the use of the TVT products.

5 Do you agree?

6 MS. GERSTEL: Object to form.

7 A. Did your statement say "all"?

8 Q. Yes.

9 A. I disagree.

10 Q. Have you ever read the

11 deposition of Ethicon's medical director

12 Dr. Robinson?

13 A. No.

14 Q. If that was the testimony, do

15 you disagree with it?

16 A. I disagree with it.

17 Q. Do you agree that doctors rely

18 on medical device companies, such as

19 Ethicon, to tell them whether the products

20 they manufacture are safe?

21 MS. GERSTEL: Object to form.

22 A. I think the company provides a

23 small piece of a doctor's understanding

24 and learning if something is safe. It's

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1 not the major role at all.

2 Q. So you believe they rely on them

3 in part for that information?

4 A. Correct.

5 Q. Do you agree that doctors rely
6 on medical device companies, such as
7 Ethicon, to investigate and test the
8 safety of their products before putting
9 them on the market?

10 MS. GERSTEL: Object to form.

11 A. I think that they are interested
12 in testing prior to release, yes.

13 Q. Is that something that you as a
14 physician want the medical device
15 providers to do?

16 A. Yes.

17 Q. Do you agree that the company
18 knows more about the design features and
19 potential risks of their products than
20 physicians do?

21 MS. GERSTEL: Object to form.

22 A. In the early development stage,
23 I would agree with you, and then when it's
24 out there, I would say there's -- you

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1 know, the doctors had the ones putting it
2 in, seeing how it behaves and seeing the

3 patients. So there are -- I think that
4 changes. I think it -- I think it changes
5 and the doctors can become more expert as
6 to efficacy and safety of the device and
7 how the features are paning out than the
8 companies who make it.

9 Q. The physicians are not privy to
10 the results of the testing and studies
11 that are done by the company prior to
12 putting the product on the market.

13 True?

14 MS. GERSTEL: Object to form.

15 A. They're privy to some of them.
16 When you have the -- typically the lead
17 inventor or authors gather data, they're
18 usually privy to that. When a company
19 would approach me with a product, first
20 thing I'd say is can you show me the data
21 you have on it, and they would share that.
22 So I am privy to the data they have.

23 They typically would not go
24 through all of the R&D bench testing, and

1 some other items would not be included in
2 that.

3 Q. Right.

4 Doctors would not be privy to
5 the bench testing results done by a
6 medical device company, such as Ethicon.

7 Right?

8 MS. GERSTEL: Object to form.

9 A. It's not routinely offered, but
10 there are certainly many times where I've
11 asked for that type of information and
12 it's been disclosed readily.

13 Q. But you had to ask for it.

14 True?

15 A. Yeah. Yes.

16 Q. Do you agree that if there's
17 reasonable association between a product
18 and an adverse event, a company should
19 disclose that information?

20 MS. GERSTEL: Object to form.

21 A. You know, the reasonable
22 association specification in your question
23 stumps me a little bit because it depends.
24 It's really -- there's a continuum of how

1 much information they get. And at a
2 certain point, if there's a very, very
3 strong relationship between a product and
4 an adverse event, yes, I think it should
5 be disclosed, but there's really a
6 continuum between how much they know and
7 when that should be shared.

8 Q. Okay.

9 So, would you agree that the
10 information that a medical device
11 manufacture, such as Ethicon, includes in
12 its IFUs should not be misleading?

13 MS. GERSTEL: Object to form.

14 A. I could agree with that.

15 Q. Do you agree that the
16 information a medical device manufacture
17 includes in its IFU should have a
18 scientific basis?

19 MS. GERSTEL: Object to form.

20 A. I think it has a scientific
21 basis, as well as a clinical experience
22 basis in terms of the things that are
23 commonly known.

24 Q. So it should be a scientific and

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1 clinical basis?

2 A. I think so, yes.

3 Q. And a medical device

4 manufacturer should put the safety of its
5 patients first.

6 True?

7 MS. GERSTEL: Object to form.

8 A. Yes.

9 Q. Even above profits.

10 Fair?

11 MS. GERSTEL: Object to form.

12 A. Yes.

13 Q. Do you agree that a medical

14 device company, such as Ethicon, is

15 required to make its products reasonably
16 safe?

17 MS. GERSTEL: Object to form.

18 A. Yes.

19 Q. Lastly, do you agree that if a

20 medical device manufacturer sells two

21 products that do the same thing, the

22 medical device manufacturer should stop
23 selling the less safe product and only
24 sell the safer product?

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1 MS. GERSTEL: Object to form.

2 A. The evidence and the data
3 distinguishing those adverse events would
4 need to be compared to get to a point
5 where it was convincing that one of them
6 definitively was as efficacious and/or
7 safer.

8 So, it's a -- it depends on the
9 level of evidence.

10 Q. Let me ask my question again.

11 Do you agree that if a medical
12 device manufacturer sells two products
13 that do the same thing, that the medical
14 device manufacturer should stop selling
15 the less safe product, assuming it's
16 definitive, and only sell the safer
17 product?

18 MS. GERSTEL: Object to form.

19 A. I can't agree with that because

20 there are situations where something has a
21 higher risk, so let's say for example leg
22 pain with an obturator sling. It's the
23 better choice, even though if you -- just
24 looking at data as a higher risk of thigh

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1 pain or leg pain, it's the better choice
2 for a patient because the patient may have
3 retropubic problems or cancer there or
4 radiation there or hernia there. So it
5 now becomes the better choice. So if
6 you're just looking at the data, you'd say
7 well, higher leg pain, maybe we shunts use
8 it. But having the two available lets you
9 go the two different routes and based on
10 patient's anatomy and doctor's
11 backgrounds, they maybe safer in different
12 doctor's hands and they also may be safer
13 based on the patient's previous surgery
14 history.

15 Q. So you can't answer my question
16 as asked, is what you're telling me?

17 A. No, I cannot.

18 Q. Have you ever read the
19 deposition of Dr. Holste?

20 A. No.

21 Q. Was that ever provided to you by
22 the defense for review?

23 A. Not that I recall.

24 Q. If that was the testimony, do

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1 you disagree?

2 A. Yes.

3 Q. Are you an expert on the design
4 of medical devices?

5 A. I think I am.

6 Q. And what qualifies you as an
7 expert on the design of medical devices?

8 A. Well, I made a really awesome
9 suturing device that allowed people to
10 suture in really small places and made a
11 whole bunch of other people millions of
12 dollars. And it's really cool and it
13 required some really neat engineering.

14 I think I have a unique
15 appreciates for the very significant

16 angles and spaces we're in in pelvic
17 surgery.

18 I think I have an intuitive
19 thought process as to how to think of
20 things that might let us do things more
21 easily.

22 I understand research design and
23 how to test things properly.

24 I think I have shown in my body

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1 of work the ability to test meshes and
2 figure out how to decrease erosions, how
3 to suture in small places. And I think
4 I've spent 25 years thinking about the
5 design of instruments and have a pretty
6 good background.

7 Q. Have you ever designed a
8 transvaginal mesh product?

9 A. I've proposed some and some are
10 under consideration, but none are
11 presently being adopted or funded for
12 production.

13 Q. Have you been --

14 MR. DeGREEFF: Strike that.

15 Q. Have you designed any mesh
16 slings?

17 A. The innovations that I have in
18 mind, which, you know, presently have been
19 proposed to a couple of engineers and it a
20 couple of companies, they have less to do
21 with the sling than with the trocar
22 introduction and so it's part of the sling
23 system, but it's not the mesh itself. I
24 would say the group that we're working

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1 with, of course, my practice, you know, as
2 the role that I play in that process, you
3 know, it's a very close division. I've
4 definitely got my eye on how absorbable
5 meshes are going to behave as we continue
6 to study them.

7 Q. So, what are the changes to the
8 trocar that you've made in these new
9 devices that you've designed?

10 A. I'm going to have to say that's
11 confidential.

12 Let me just clarify that to give
13 you something.

14 I think that we -- sometimes
15 when you pass a trocar and you did
16 cystoscopy because you want to see if the
17 pass went into the bladder and sometimes
18 it's missed even though trocar looks
19 pretty big under cystoscopy. So I have a
20 design proposal that would decrease or
21 eliminate the chances of missing a very
22 small passage into the bladder.

23 Q. What weight of mesh do you use
24 in the -- in your new products?

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1 A. I haven't gotten to the point of
2 choosing the mesh. I'm only designing the
3 trocar. So the mesh would be -- there's
4 two companies it's proposed to and the
5 mesh would be whichever company decided to
6 move this forward, I'm comfortable with
7 both of their sling products. So you have
8 both Caldera and Boston Scientific looking
9 into this. So it would be their meshes

10 and it would just be changing the trocar
11 insertion.

12 Q. What weight of mesh do Boston
13 Scientific and Caldera use?

14 A. I don't have their mesh weight
15 by memory. They're all type 1 wide pore
16 mesh.

17 Q. Why did you not go to Ethicon
18 for their mesh?

19 A. I've had a closer working
20 relationship with these two companies for
21 the past five, six years.

22 Q. Does the Ethicon product have
23 smaller pore mesh than BSC and Caldera?

24 A. They're pretty close. I think

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1 Caldera is less, is smaller. I don't
2 recall where Boston Scientific is related
3 to TVT.

4 Q. Well, Caldera is actually larger
5 pore mesh than the Ethicon product.

6 Correct?

7 A. I'm not sure about that.

8 Q. What about BSC is actually a
9 larger pore mesh than Ethicon mesh too.

10 Right?

11 MS. GERSTEL: Object to form.

12 A. I don't have those comparisons
13 in my head.

14 What I know is that they're all
15 in the order of ten times wider pores than
16 what is felt to be the minimum necessary
17 for favorable characteristics as described
18 by AMA.

19 Q. Regardless, when you decided you
20 needed mesh for a product you're
21 developing, you sought that mesh from
22 Caldera and Boston Scientific, not from
23 Ethicon.

24 True?

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1 A. I wasn't seeking mesh. I was
2 seeking someone who thought an
3 introduction needle had an advantage.

4 Q. Okay.

5 The two companies you went to

6 for your product were Caldera and BSC, not
7 Ethicon.

8 True?

9 A. Yes.

10 Q. And you could have gone to
11 whatever companies you wanted to.

12 Right?

13 A. Yes.

14 Q. And you had a working
15 relationship with Ethicon.

16 Right?

17 A. Yes.

18 Q. When was this that you were
19 approaching these companies?

20 A. In the past two years.

21 Q. So you had a relationship with
22 the company in Ethicon that has paid you
23 200 to \$250,000 as a litigation expert.

24 Right?

123

1 MS. GERSTEL: Object to form.

2 A. Yes.

3 Q. Has Ethicon ever asked you to

4 consult on the design of any of their mesh
5 products?

6 A. I was in a consulting R&D
7 session on whether or not to make the
8 trocar smaller when they were considering
9 the TVT Exact. So that's not a mesh
10 decision, but again part of the mesh
11 system. I know they were interested in
12 what I thought of the Gynecare mesh just
13 because I had used it a lot. So, it
14 wasn't -- the Gynemesh had been, you know,
15 a smaller cut piece of a previous type of
16 mesh they had previously used. So they
17 were interested in a lot of my input
18 because they know I used it a lot and I
19 published on it. So they asked if they
20 could do anything different with it and I
21 said my patients are doing extremely well,
22 so I'm happy with it.

23 Q. Gynecare mesh were use that go
24 for pelvic organ prolapse?

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1 A. Yes. And there was a time when

2 I was using it for individually cut sewed
3 prolapse vaginal procedures.

4 Q. As you sit here today, it's no
5 longer possible to use Gynecare for repair
6 of pelvic organ prolapse.

7 Correct?

8 MS. GERSTEL: Object to form.

9 A. I'm not doing it at all.

10 Q. You don't have any --

11 MR. DeGREEFF: Strike that.

12 Q. You don't have any patents on
13 medical devices currently.

14 True?

15 A. Correct.

16 Q. Did you have involvement with
17 the design of the Solyx, the Boston
18 Scientific Solyx?

19 A. We may have mentioned this
20 before. That was the one time where I
21 was -- yes, I was in their R&D labs giving
22 them feedback on pre-release research and
23 development design phase and a positive
24 and negative feedback on it, which was on

1 their company documents, which ended up
2 with me in a deposition not on either
3 side, just called to be deposed on what I
4 had written in that R&D lab.

5 Q. Are you familiar with the
6 industry standards that govern medical
7 device design?

8 MS. GERSTEL: Object to the
9 form.

10 A. I'm familiar with a number of
11 the FDA standards.

12 Q. What are those regulatory
13 standards?

14 A. Well, there's clearances and
15 approval processes they have to go
16 through. There's device labeling
17 instructions.

18 Q. Anything else that you can think
19 of?

20 A. There's classifications that
21 tell you how much -- whether something is
22 based on something previous, how much data
23 needs to come before release.

24 Q. Have you reviewed any Ethicon

1 internal standards on medical device
2 design?

3 A. I don't recall.

4 Q. Are you familiar with the stage
5 gate system?

6 A. I am not.

7 Q. Do you know what a clinical
8 expert report is?

9 A. I think it's a -- it's a
10 detailed statement on where the company
11 feels a product is in terms of its
12 research and development. I'm not certain
13 on that.

14 Q. Have you reviewed any of
15 Ethicon's clinical expert reports related
16 to the TVT mesh sling products?

17 A. Since the title sounds familiar,
18 I think I read one, and I don't recall
19 which one it was or any of the details,
20 but I think I -- it was in front of me at
21 one point.

22 Q. As you sit here, you just don't

23 remember anything about what it said?

24 A. No.

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1 Q. True?

2 A. Correct.

3 Q. Do you know what a design
4 history file is?

5 A. No, but the name kind of gives
6 it away. But the answer to your question
7 would be no.

8 Q. Have you ever reviewed the
9 design history file, Ethicon's design
10 history file with regard to any of the TVT
11 products?

12 A. I can tell you that I've read
13 quite a number of documents that describe
14 the evolution of the TVT products. I
15 don't know if that's within that stated
16 document.

17 So, the answer is that document
18 by name I'm not familiar with, but I'm
19 certainly familiar with many documents
20 that describe the evolution of the TVT and

21 the TVT product family.

22 Q. What is contained in the design
23 history file?

24 A. Since I haven't seen the file,

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1 I -- I can't tell you.

2 Q. So, as you sit here, is it fair
3 to say you don't know whether you've
4 reviewed the design history file or not?

5 A. Correct.

6 Q. What employees from Ethicon were
7 involved in the design of the TVT
8 products?

9 A. Well, the key ones were Olmstead
10 for the TVT and De Lara for the obturator
11 products.

12 Q. Have you read those depositions?

13 MS. GERSTEL: Object to form.

14 A. I have not read their
15 depositions, no.

16 Q. Were those depositions given to
17 you by defense counsel?

18 MS. GERSTEL: Object to form;

19 lack of foundation.

20 A. I don't recall them being given
21 to me.

22 Q. What is Med Scan?

23 A. Is that the Canada group?

24 No?

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1 I don't know what it is.

2 Q. What is Provincia?

3 A. I don't know.

4 Q. Do you know what a design
5 failure modes and effects analysis is?

6 A. Say it again. Design failure?

7 Q. Modes and effects analysis.

8 A. I couldn't describe it to you
9 specifically.

10 Q. Ever participated in one?

11 A. Well, if putting something on
12 tension to seeing load failure and various
13 other changes in the characteristics of
14 the mesh when you do different things to
15 it is part of it, then yes.

16 Whether I knew that I was

17 specifically in a session that was labeled
18 that, I don't recall that it had that
19 name.

20 Q. What are the different types of
21 failure modes and effects analysis?

22 A. Can't answer that.

23 Q. Just don't know?

24 A. Correct.

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1 Q. Did you review any of the design
2 failure modes effects analysis on the TVT
3 mesh slings?

4 A. I may have, but not knowing it
5 had that title.

6 Q. As you sit here, you just don't
7 know whether you did or not?

8 A. Correct.

9 Q. Are you aware of any company
10 other than Ethicon that marketed a -- that
11 marketed mesh that was mechanical-cut?

12 MS. GERSTEL: Object to form.

13 A. Caldera's is mechanically-cut.

14 Q. Which product?

15 A. The Desara and the Desara TV
16 Blue. There may be others, but I know
17 that that one is.

18 Q. Have you ever reviewed any of
19 Ethicon's internal operating procedures
20 related to design?

21 A. I've read a lot of pages that
22 discuss how -- how a procedure is going to
23 be designed. And again, whether it had
24 that title, I don't know. I've recently

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1 read a number of Ethicon documents that
2 are discussing the process for design and
3 feasibility and opinions as to where the
4 product stands.

5 Q. So you don't know if you've
6 reviewed the standard operating procedure
7 or not.

8 True?

9 A. Specifically the document by
10 that name, no.

11 Q. How long did it take Ethicon to
12 get the TVT-0 product to market?

13 A. I don't know. From first
14 thought to mind to market, I don't know
15 that answer.

16 Q. Is it ever a good idea to rush a
17 product to market?

18 MS. GERSTEL: Object to form.

19 A. The product's got to get to
20 market in a time frame that when it's felt
21 to be efficacious and safe.

22 Q. Have you ever reviewed any
23 Ethicon internal documents discussing how
24 quickly they got the TVT-0 to market?

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1 A. No.

2 Q. That's not something that was
3 ever provided to you?

4 A. Not that I recall.

5 Q. Of the opinions you --

6 A. I'm going to correct that.

7 I seem to now have refreshed my
8 memory. I recall -- I can't recall
9 exactly. The theme of one company
10 document had to do with a need to -- a

11 wish to get this removing along based on
12 competition. I do remember a document
13 that had that type of theme.

14 Q. Is it your understanding that
15 Ethicon wanted to get the TVT-0 to market
16 as quickly as possible?

17 MS. GERSTEL: Object to form.

18 A. The only thing I recall was that
19 there was -- there was wording that
20 expressed a wish for it to be released and
21 the timing of the release was important
22 based on competition.

23 Q. So they wanted to beat the
24 competitors to the market.

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1 Is that what you're saying?

2 MS. GERSTEL: Object to form.

3 A. I said what I said.

4 Q. Well, they wouldn't want the
5 competitors to get there first.

6 Right?

7 MS. GERSTEL: Object to form.

8 A. The competitors were there.

9 Q. Okay.

10 The opinions you're giving in
11 this litigation with regard to the TVT-0,
12 TVT-A, TVT-Exact, have you ever published
13 those in any peer-reviewed journal?

14 A. No.

15 Q. Have you ever been involved in
16 any clinical trials comparing midurethral
17 slings to any other pelvic surgery?

18 MS. GERSTEL: Object to form.

19 A. Comparative trial, no.

20 Q. Have you ever been involved in a
21 randomized controlled trial involving
22 transvaginal mesh treatment of stress
23 urinary incontinence?

24 A. No.

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1 Q. What antioxidants are added to
2 the TVT mesh slings?

3 A. I do not know.

4 Q. What is the pore size of the
5 Prolene mesh in the TVT products?

6 A. It's in the 1300 range.

7 Q. And it's the same for all of the
8 sling products we're talking about, right?
9 The TVT-0, the TVT-Abbrevio and the
10 TVT-Exact?

11 A. Yes.

12 Q. Have you ever heard that pores
13 in mesh collapse?

14 A. I have not.

15 Q. Do you agree that if mesh pores
16 are not large enough, there can be an
17 increased risk of infection?

18 A. Yes.

19 Q. Do you agree that if pores are
20 not large enough, it increases the risk of
21 erosion?

22 A. Potentially, secondary to the
23 first discussion we had about infection.

24 Q. Do you agree that if pores are

135

1 not large enough, there can be poor tissue
2 integration that can cause mesh rejection?

3 A. Yes.

4 Q. Do you agree that you can get an

5 infection with small pore mesh causing
6 extrusion?

7 A. Yes.

8 Q. Do you agree that mesh with
9 smaller pores tends to have a greater
10 inflammatory response than mesh with
11 larger pores?

12 MS. GERSTEL: Object to form.

13 A. Yes.

14 Q. What is the weight of the mesh
15 in the TVT family of slings?

16 A. I don't have that data.

17 Q. Why does Ethicon call the
18 Prolene mesh used in the TVT slings old
19 construction mesh?

20 MS. GERSTEL: Object to form;
21 lack of foundation.

22 A. I think terminology regarding
23 the Ethicon family of meshes and names
24 given to them have mistakes and confusion,

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1 and everything we're talking about in all
2 four of these slings is type 1 wide pore

3 mesh.

4 MR. DeGREEFF: I'll move to
5 strike as non-responsive. That wasn't
6 the question that was asked.

7 Q. My question was --

8 MR. DeGREEFF: Strike that.

9 Q. Do you know what I mean when I
10 say old construction mesh?

11 MS. GERSTEL: Object to form.

12 A. There are different ways the
13 meshes were put together over time.
14 They're woven differently. They have
15 different fiber sizes, different pore
16 sizes. So, you know, the Prolene mesh has
17 a long history to it.

18 So, the -- the way it was
19 constructed was different in older, or
20 let's say times past, was made differently
21 than it is now.

22 Q. Well, the mesh currently used in
23 the TVT sling products was originally
24 developed for hernia repair.

1 True?

2 A. Yes.

3 Q. And it was developed for hernia
4 repair in the gut.

5 Fair?

6 A. Yes.

7 Q. It was not originally developed
8 or designed to be implanted in the vagina.

9 True?

10 A. Originally, yes.

11 Q. And the mesh used in the TVT
12 products was originally developed in 1974.

13 Is that true?

14 A. I don't have that knowledge of
15 the date.

16 Q. It was a long time ago, right,
17 when it was developed?

18 A. If that's the correct date, it's
19 the number of years that it is. It's been
20 working well for all these years.

21 Q. It's almost a half century ago.

22 Right?

23 A. Yeah. It's been working well
24 for 20 years.

1 MS. GERSTEL: As someone who has
2 gave birth close to that year, I take
3 offense to that part.

4 MR. DeGREEFF: Trust me, I'm
5 real close to that too.

6 Anybody need to take a break?

7 MS. GERSTEL: Sure.

8 (Recess taken.)

9 (Lind Exhibit 7, Defense Expert
10 General Report of Lawrence Lind, M.D.
11 re TVT, TVT-0, TVT-Exact and
12 TVT-Abbrevio, June 24, 2019, was marked
13 for identification, as of this date.)

14 (Lind Exhibit 8, Lawrence Lind
15 Supplemental General Materials List in
16 Addition to Materials Referenced in
17 Report, was marked for identification,
18 as of this date.)

19 BY MR. DeGREEFF:

20 Q. Sir, I'm handing you what has
21 been marked as Deposition Exhibit 7.

22 Can you tell us what that is?

23 A. It looks like my defense expert

24 general report for TVT, TVT-0, TVT-Exact

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1 and TVT-Abbrevio.

2 Q. Sir, does this report contain
3 all of your opinions related to those
4 products?

5 MS. GERSTEL: Object to form.

6 A. No.

7 Q. What isn't in your report?

8 A. In preparing for the deposition,
9 I have continued to read, continued to
10 pull more articles, and continued to
11 educate myself.

12 Q. Sir, do you understand that in
13 this litigation, there's a deadline for
14 disclosing expert opinions?

15 A. Okay.

16 Q. Do you understand that deadline
17 has passed?

18 A. Okay.

19 Q. So, what opinions did you not
20 include in your report that you now intend
21 to offer?

22 A. I just have a little more detail
23 on some adverse events and some -- it's
24 really the studies are in there and it's

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1 really just a little more in-depth
2 understanding of what the studies have
3 shown.

4 So, I'm not adding studies to
5 the report. I'm just a little more
6 familiar with the drill-down ordeal of
7 what's within the studies.

8 Q. I think we're talking about two
9 different things, and you're talking about
10 the materials you relied on in support of
11 your opinions.

12 Correct?

13 A. Correct.

14 Q. I'm talking about the opinions
15 you've given in your report, the general
16 opinions regard to the TVT, TVT-0, the
17 TVT-Exact and TVT-Abbrevio.

18 Are all of those opinions that
19 you intend to give at trial contained in

20 this report?

21 A. Well, if the legal rules are
22 such that those are the limits, then those
23 will have to be the limits.

24 I have additional thoughts, and

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1 you will guide me as to the legal process.

2 Q. Have you been asked by defense
3 counsel to provide any additional
4 opinions?

5 A. No.

6 Q. Is it your intention at trial to
7 provide any opinions that are not
8 contained in your report?

9 MS. GERSTEL: Object to form.

10 A. I will follow whatever the legal
11 guidelines are. And if I'm able to speak
12 opinions that are not specifically in
13 there, I will, and if I'm instructed that
14 I'm not allowed to do it, I'll follow the
15 instructions.

16 Q. Okay. Well, tell me what the
17 additional opinions are that you have as

18 you sit here that are not contained in
19 your report.

20 MS. GERSTEL: Object to form;
21 asked and answered.

22 A. There are details, there are
23 studies which I discuss in here and I give
24 opinions were those reports, and I have

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1 more information from those same studies
2 which I feel is additive to my opinions.

3 Q. Do those studies, in any way,
4 alter your opinions?

5 A. They strengthen my opinions in
6 the same direction.

7 Q. So none of your opinions
8 contained in your report are going to
9 change?

10 A. Correct.

11 Q. So there is no new category of
12 opinion that you plan to provide. What
13 you're saying is you believe that you have
14 a better understanding now of some of the
15 materials you've -- or, I guess, materials

16 you've already cited in your report.

17 Fair?

18 A. I think I have information that
19 strengthens the opinions that I give.

20 Q. Okay.

21 But nothing will alter the
22 opinions?

23 A. Correct.

24 Q. Have you prepared any kind of a

143

1 supplemental report?

2 A. No.

3 Q. So, what is it that you want to
4 add to the report that strengthens your
5 analysis of these materials?

6 MS. GERSTEL: Object to form.

7 A. Well, for example, you know, a
8 report quoted often is the Schimpf
9 meta-analysis and a high rate of leg or
10 groin pain.

11 Q. Okay.

12 A. And that kind of jumped off the
13 page at me as something that seemed out of

14 line with a lot of the reading I have done
15 and my personal experience. So I decided
16 to explore that pain because I think we
17 can all agree that if someone has an
18 incision in the groin, it would make sense
19 that they would have pain, some degree.
20 Let's not say much degree. Anywhere you
21 have an incision there's going to be pain
22 immediately postoperatively.

23 For the -- for the TVT, there's
24 pain where the trocars come out of the

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1 suprapubic region. Right after and for
2 the groin where it comes out. And what's
3 of important interests is how severe is
4 the pain and how long does it last. So
5 that number that jumps off the page which
6 a lot of people react to as a high leg
7 pain rate, I wanted to explore that
8 further. So I researched and found the
9 seven randomized control trials that go
10 into making that 16.7 percent and the data
11 from those trials clearly indicates that

12 clearly the preponderance, or at least 90
13 percent of the data shows that all of the
14 pain goes away within a few weeks to a
15 month. So, most of the data supporting
16 that 16.7 is transient pain, which I think
17 is very relevant as opposed to just the
18 number of 16.7. In the Ford Cochrane
19 analysis, which is also included several
20 times in my report, supports that leg pain
21 tends to be transient. So that's one
22 example of an expansion or a deeper dive
23 into a study to say what is the 16.7
24 percent in the Schimpf article mean, and

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1 doing some real research, we can say
2 what's the body of literature that goes
3 into the real number.

4 Q. What other opinions do you want
5 to add?

6 A. I would say I've seen an article
7 by Teo which is quoted and it certainly
8 sparks a lot of attention because it's a
9 trial where they decided to stop the

10 trial, feeling it would be immoral to
11 continue the trial because they had read
12 other articles that showed a high
13 incidence of groin pain and that it would
14 be -- it would be immoral to continue the
15 trial.

16 I said well, let me look into
17 it. It really seems, again, what was the
18 data that was so alarming and what was
19 going on in their study. And in their
20 study, when they stopped the trial, almost
21 all the patients who had groin pain had it
22 resolved within a couple of weeks and
23 there was only one patient who had chronic
24 groin pain and it was a patient in the TVT

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1 group. So I thought it was very
2 interesting that a study that is quoted
3 often as to how problematic that is a
4 study had to be stopped because of the
5 high level of groin pain reported
6 elsewhere was in the middle of a study
7 demonstrating extremely little groin pain

8 and the only patient having prolonged
9 problems was in the other group. So I
10 think it's -- my main message is that if
11 you dive into deeper into the literature,
12 the specifics about the groin pain and how
13 often it is severe or prolonged very
14 strongly is compelling that the pain is
15 transient.

16 Q. Okay. What else? What other
17 opinions do you want to add?

18 A. I would add an opinion on the
19 Okulu article. Okulu used Vypro and
20 absorbable mesh compared to two others for
21 a sling and it's a very strongly presented
22 as evidence that there was a better
23 material, better alternative to the TVT
24 type mesh for slings. And I think it's,

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1 number one, it's unreasonable to use that
2 as evidence that a TVT could be done
3 better with this material because the --
4 in taking a deeper dive it became clear to
5 me this they don't do a procedure that

6 looks anything like a TVT. They make a
7 vaginal flap, a very large vaginal flap
8 and open a big incision, which TVT does
9 not. They cut out and island of vaginal
10 tissue and they sew a piece of this mesh
11 on top of the vaginal tissue and then they
12 use sutures it make a hammock out of it.

13 So, the procedure, while in that
14 study shall I get that it showed that the
15 absorbable mesh had some favorable
16 characteristics compared to the
17 non-absorbable, it was describing a
18 procedure that someone invented that
19 doesn't exist anywhere else in the
20 literature. So I wanted to look a little
21 further into, you know, what is the
22 evidence for Vypro and the absorbable
23 meshes because the case that there's an
24 alternative that's more favorable is very

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1 important, I think, to our discussion in
2 weighing the pluses and minuses here. So
3 a did a literature search on Vypro mesh

4 and there are 72 articles on a Pub Med
5 search. If you look for Vypro. And while
6 there are a -- if you research midurethral
7 sling, you'll get about 4,000 and when you
8 research Vypro mesh, you'll get 72. And
9 there are precisely two articles related
10 to slings, and there are three articles,
11 there are more articles in the Vypro Pub
12 Med search on using it for mosquito
13 netting than there are on using it for
14 slings much and the remainder of this are
15 related to non-incontinence procedures.

16 So, I think it's -- my main
17 opinion that I'm adding is that the main
18 study used that's comparative is on a
19 procedure that doesn't resemble a TVT at
20 all. So I think it's unfair to say that
21 for a TVT this would be better. And that
22 the data that's available for Vypro in the
23 incontinence world is microscopically
24 small compared to unprecedented data in

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1 favor of the TVT product which we're

2 discussing. So that's an additional
3 opinion I would give.

4 Q. How many of those articles
5 related to the TVT are long-term
6 randomized controlled trials with safety
7 as the primary endpoint?

8 MS. GERSTEL: Object to form.

9 A. About 85.

10 Q. Which long-term randomized
11 control trials exist on the TVT?

12 MS. GERSTEL: Objection to form.

13 A. 417 had I believe 81 or 85
14 randomized controlled, I can't name them
15 all, and they had about 13,000 patients.

16 Q. Anything else you want to add?

17 I just want to know so I can
18 move to have them stricken.

19 MS. GERSTEL: I'm sorry?

20 MR. DeGREEFF: I just want to
21 know so I can move to have them
22 stricken.

23 BY MR. DeGREEFF:

24 Q. Doctor, were all these articles

1 that you're talking about now available to
2 you before you rendered your opinions in
3 this case?

4 A. The Okulu article was available
5 and is quoted in my paper, but in
6 reviewing my expert report and preparing
7 for this, I read through that article and
8 I -- when I noticed that it didn't look
9 anything like a sling and that it was new
10 information for me, that it really was not
11 a minimally invasive TVT type procedure, I
12 said to myself gosh, if this is so
13 different, I'm curious how much we know
14 about this. So I looked further.

15 So, in reviewing my present
16 statements, new curious tees developed, so
17 I researched them.

18 Q. Yeah, that's information that
19 was available to you though prior to
20 issuing your opinions.

21 Right?

22 A. I guess the whole world of
23 articles was available to me.

24 Q. Nothing new came out between the

1 time you wrote your report and now.

2 Right?

3 A. Well, there have been articles
4 that have come out, but not -- I don't
5 think we're speaking about new articles
6 that came out that are relevant to your
7 discussion right now.

8 Q. None of the articles that you
9 have now reviewed and wish to add opinions
10 on were unavailable at the time you
11 originally authored your opinions.

12 True?

13 MS. GERSTEL: Object to form.

14 A. That's correct.

15 Q. This was something that you
16 decided to look in after having been
17 deposed previously on the TVT.

18 Is that fair?

19 A. Well, from a time sequence, it
20 would be after the TVT, but it wasn't from
21 the TVT that had me do it. I was reading
22 my report four days ago and these elements

23 just came to mind. So this was based on
24 things that came to mind in reading

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1 through my report preparing this week.

2 Q. Because those articles that you
3 now seek to attack, those results are bad
4 for the TVT products.

5 Right?

6 MS. GERSTEL: Object to form.

7 A. Which articles are bad?

8 Q. The ones you're talking about
9 that you now wish to further clarify.

10 Those results are adverse to the
11 TVT products.

12 Right?

13 MS. GERSTEL: Object to form.

14 A. Well, I think they're -- I think
15 they're kind of good for my argument
16 because they -- Okulu really doesn't
17 describe a TVT procedure. So I would
18 consider it a strong defense that we're
19 trying to suggest something's an
20 alternative when it's really not doing the

21 procedure that we're interested in.

22 Q. No, I understand you think you
23 can attack those conclusions somehow.

24 But my question is the reason

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1 you started looking into those articles is
2 because the results on their face are bad
3 for the TVT products.

4 True?

5 MS. GERSTEL: Object to form.

6 A. The studies didn't make sense to
7 me. The reason I looked at everything I
8 had in my report and if something came to
9 me that seemed curious or in question,
10 like the 16.7 percent erosion, it just
11 didn't seem right. So I'm a curious guy
12 and I look into things and I looked into
13 it. I didn't go after it because it was
14 negative. I went after it 'cause it
15 didn't make sense to me.

16 Q. But it was negative.

17 Right?

18 A. I would say the Schimpf article

19 was misleading.

20 Q. Is 16.8 erosion rate, is that an
21 acceptable rate to you?

22 MS. GERSTEL: Object to form.

23 A. It's a rate that's misleading
24 because that's immediately postoperative

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1 and that's what's wrong with her data.

2 Q. I understand that you want to
3 attack an author who wrote a -- something
4 that was actually published on the TVT
5 products.

6 My question is 16.8 percent
7 erosion, is that an acceptable erosion
8 rate to you?

9 MS. GERSTEL: Erosion?

10 A. Are you speaking of erosion or
11 leg pain because the Schimpf?

12 Q. I'm sorry. Leg pain.

13 MR. DeGREEFF: Strike that.

14 Let's start over.

15 A. So, my answer to that would be
16 in the immediate postoperative period, I

17 think it's a very low rate of pain where
18 there's an incision and completely
19 acceptable.

20 If that is prolonged or severe
21 and prolonged, I would consider that
22 unacceptable.

23 Q. What is an acceptable rate of
24 chronic groin or leg pain?

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1 A. Well, everyone would have a
2 different cutoff because you're balancing
3 the risks and benefits of each sling.

4 So, you know, I think that in
5 the 2 to 4 percent range is acceptable,
6 and we have to accept that in the
7 understanding that we are decreasing
8 bladder perforations, bowel perforations
9 with the TVTs. So it's not just does the
10 patient have leg pain. It's what we're
11 trading.

12 MR. DeGREEFF: Move to strike
13 non-responsive.

14 Q. My question was just simply what

15 is an acceptable rate in your mind of
16 chronic groin and leg pain from a TVT
17 implant?

18 MS. GERSTEL: Object to the
19 form.

20 A. I would say in the 2 to 3
21 percent.

22 Q. So, your report, which is
23 Exhibit 7, is 57 pages long.

24 True?

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1 A. Yes.

2 Q. I believe we discussed
3 earlier --

4 MR. DeGREEFF: Well, strike
5 that.

6 Q. Who wrote that report?

7 A. I did.

8 MS. GERSTEL: Objection; subject
9 to privilege.

10 BY MR. DeGREEFF:

11 Q. Did you write the whole thing?

12 MS. GERSTEL: Objection.

13 Subject to privilege under the Federal
14 Rules of Civil Procedure.

15 Don't answer.

16 MR. DeGREEFF: I can ask that.

17 I don't get to see drafts, but I can
18 ask who wrote it.

19 MS. GERSTEL: No, you can't ask
20 about the report writing process.

21 MR. DeGREEFF: I absolutely can,
22 but that's not where I'm going with
23 this anyway.

24 BY MR. DeGREEFF:

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1 Q. Who wrote that report?

2 MS. GERSTEL: Objection.

3 Don't answer. Subject to
4 peripheral.

5 BY MR. DeGREEFF:

6 Q. Are you going to choose to
7 accept your counsel's request that you not
8 answer my absolutely proper question.

9 A. Yes.

10 MR. DeGREEFF: Moving forward,

11 you guys won't get anything from us.

12 BY MR. DeGREEFF:

13 Q. So, did you actually physically
14 write every word of it?

15 MS. GERSTEL: Objection. Same
16 basis.

17 Don't answer.

18 A. I'm declining to answer.

19 Q. Are there any parts of that
20 report that came from other people's
21 reports?

22 MS. GERSTEL: Same objection.

23 Don't answer.

24 MR. DeGREEFF: I absolutely can

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1 ask that. That is 100 percent
2 correct. If he's pulled pieces of a
3 report from other individuals' expert
4 reports, I have every right to know
5 that.

6 MS. GERSTEL: It's all covered
7 by --

8 MR. DeGREEFF: No, it's not

9 covered by that.

10 MS. GERSTEL: It is.

11 MR. DeGREEFF: No, it's really
12 not.

13 MS. GERSTEL: It is. I'm
14 directing him not to answer.

15 MR. DeGREEFF: Okay.

16 BY MR. DeGREEFF:

17 Q. Why do you think your counsel
18 doesn't want you to tell me who wrote your
19 report?

20 MS. GERSTEL: Objection.

21 A. I don't know whether there are
22 legal guidelines that she feels give that
23 that's the way it's supposed to go.

24 Q. Do you think if you wrote the

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1 whole thing, she'd let you answer?

2 MS. GERSTEL: Objection.

3 Don't answer that.

4 A. I'm declining to answer.

5 Q. So, it took you 25 hours to
6 write a 57-page report.

7 Is that right?

8 A. Right.

9 Q. Your report also has a reliance
10 list along with it. That's Exhibit 8.

11 Correct?

12 A. Right.

13 Q. Are you aware it was amended
14 five days ago?

15 A. I remember I had come up with
16 some articles that I had wanted to
17 include.

18 Q. What was added to it?

19 A. I don't recall specifically at
20 the moment.

21 Q. Who chose the materials that
22 were added to it?

23 A. I did.

24 Q. All of them?

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1 A. All of them.

2 Q. Who drafted the additions to the
3 reliance list?

4 A. The reliance list, the typed

5 reliance list was done by counsel.

6 Q. Okay.

7 A. The input to the reliance list
8 this week was mine.

9 Q. So, this reliance list was
10 supplemented because you came up with
11 additional articles that you reviewed in
12 preparation for your deposition.

13 Is that true?

14 MS. GERSTEL: Object to the
15 form.

16 A. I think there's also one or two
17 that were in my report which we did not
18 have on there. So there were a couple of
19 articles that I added and a couple that
20 were erroneously that were not added that
21 were already on the report.

22 Q. Okay.

23 So, is everything --

24 MR. DeGREEFF: Strike that.

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1 Q. Does your supplemental reliance
2 list, together with your report, contain

3 everything that you reviewed in rendering
4 your general opinions?

5 A. As I stated previously, I have
6 read additional materials all week and
7 have some other things in my head, and I
8 do understand that you have legal reasons
9 for why I may or may not be able to use
10 those you, but -- so there would be some
11 that I reviewed that are not in there.

12 Q. Well, your reliance list was
13 just supplemented five days ago.

14 Have you reviewed additional
15 materials since then?

16 A. I have.

17 Q. The materials that you added to
18 your reliance list, were you directed by
19 counsel to look into certain issues?

20 MS. GERSTEL: Objection.

21 BY MR. DeGREEFF:

22 Q. Is that why you started to look
23 into them?

24 MS. GERSTEL: Objection. That's

1 will go under privilege.

2 Communications between experts and
3 counsel are privileged.

4 MR. DeGREEFF: That's a
5 privilege?

6 MS. GERSTEL: Yes, under the
7 rules. We can look at it right now.

8 MR. DeGREEFF: Not if they rely
9 on it.

10 MS. GERSTEL: I'm sorry?

11 MR. DeGREEFF: Not if they rely
12 ton. If he takes actions what you're
13 telling him to do.

14 MS. GERSTEL: No, communications
15 between expert and counsel are
16 privileged.

17 MR. DeGREEFF: If you provide
18 information ultimate relied on, then
19 I'm entitled to discovery.

20 MS. GERSTEL: The communications
21 are qualified under peripheral except
22 to the extent that they pertain to --

23 MR. DeGREEFF: I'm not asking
24 what was said. I'm asking if he was

1 directed to do a search.

2 MS. GERSTEL: That pertains to
3 communication between me and him.

4 MR. DeGREEFF: You and I are
5 going to have to disagree on that.

6 BY MR. DeGREEFF:

7 Q. In rendering the general
8 opinions that you've got in your report,
9 is everything that you relied on in giving
10 those opinions contained in your reliance
11 list or the report itself?

12 MS. GERSTEL: Object to the
13 form.

14 A. Say that again.

15 Q. Is everything you relied on in
16 rendering your opinions --

17 MR. DeGREEFF: Strike that.

18 Q. Are all the materials you relied
19 on in rendering the opinions in your
20 report contained in either your report or
21 the supplemental reliance list?

22 A. No, 'cause I also depend on
23 knowledge learned from courses, books,

24 reading, education, clinical experience,

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1 discussion with other experts, all the
2 time I spent in R&D labs.

3 So, my reliance is not just on
4 articles. So I've had 25 years of
5 learning that come from sources that are
6 other than articles.

7 Q. Let's try this again. I think
8 if you listen to my question, it will be
9 okay.

10 Are all of the materials,
11 materials, you're not a material, as far
12 as I'm aware of, but are all of the
13 materials you relied on in rendering the
14 opinions in your report contained in
15 either the supplemental reliance list or
16 the report itself?

17 A. When I go to courses, there are
18 materials, entire binders that have
19 information.

20 Q. Are those on your reliance list?

21 A. No. I've learned them over the

22 years.

23 Q. Why not?

24 A. Because they're in my brain. I

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1 have them.

2 Q. Do you understand that I have
3 the right to understand and know about and
4 see all of the materials you relied on in
5 reaching your opinion?

6 A. I think you're totally
7 reasonable, and I am certainly not trying
8 to be difficult. But when you say when I
9 made opinions, what I have told you I also
10 have from opinions which is the knowledge
11 that's in my brain from the sum total of
12 places I've gathered information, that's
13 part of where my opinions came from.

14 And if the word "materials" is
15 something for us to focus on, in many of
16 the places where I learned there were
17 materials. I can't produce them. If that
18 makes it illegal to be part of this, you
19 know, you'll instruct me on that, and you

20 and Diana will discuss that. But my
21 opinions have a lot that comes from a lot
22 of different sources of learning that
23 don't have materials that can be put into
24 the reliance list.

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1 Q. I want a copy of the materials
2 you're talking about that I haven't seen.

3 Do you have copies of them?

4 A. I have some of them. Yeah.

5 MR. DeGREEFF: I would like you
6 to give your counsel all of them and
7 then she can produce them to me.

8 Is that okay with you?

9 THE WITNESS: I'll give you what
10 I have, just clarifying that it won't
11 be the full complement of every
12 educational piece that I have. But I
13 do have quite a few.

14 MR. DeGREEFF: Whatever you
15 claim to be relying on, I want to see
16 a copy of it. So please give it to
17 your counsel.

18 MS. GERSTEL: Are you talking
19 about every textbook he read in
20 medical school?

21 MR. DeGREEFF: Right. Or at
22 least identify it. They haven't been
23 identified.

24 Well, I mean if we're going to

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1 play this game, we're going to play
2 this game.

3 MS. GERSTEL: I'm not trying to
4 play a game.

5 MR. DeGREEFF: If that's the way
6 we're going to play, if that is the
7 game you want to play, then that is
8 the game we're going to play.

9 MS. GERSTEL: I'm not trying to
10 play a game.

11 I'm just saying that he's a
12 urogynecologist and his opinions on
13 urogynecology are based in part on his
14 sum total of experience in practice
15 and in learning as a urogynecologist.

16 MR. DeGREEFF: That's not the
17 response to my question. My question
18 is very simple.

19 BY MR. DeGREEFF:

20 Q. What materials am I going to see
21 that you're going to talk about at trial
22 in support of your opinions that are not
23 included in either your reliance list,
24 your supplemental reliance list, or your

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1 report?

2 A. Well, I would say if I rendered
3 the opinions from the items that I learned
4 outside of these materials that you have
5 in front of them, they're going to be
6 presented in the same way as part of my
7 experience and knowledge as a
8 urogynecologist. I'm not going to show up
9 with binders and binders of things that
10 you haven't had a chance to look at in the
11 proper process.

12 Q. Well, if there are materials
13 that you are going to rely on that are not

14 on your reliance list, identify them and
15 give them to your counsel, please.

16 So, can you identify them right
17 now for me?

18 MS. GERSTEL: Objection.

19 A. There's binders and binders of
20 course materials I've taken every year I
21 take one or two courses. There's the --
22 every year I update and I get the binder
23 for the female pelvic medicine fellowship
24 board certification course. It's, you

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1 know, it's like three of these binders.
2 And, yeah, I mean, I'll get you -- if you
3 said you want everything that I have, I'll
4 get you everything I have.

5 BY MR. DeGREEFF:

6 Q. Are those things on your
7 reliance list?

8 A. Well, I would say that the
9 course, let's say the 2018 fellowship
10 review course binder instruction and
11 educational materials, that is not on my

12 reliance list. There are certainly
13 hundreds of articles from that course that
14 are on my reliance list because a number
15 of topics in that course are slings,
16 efficacy and safety of slings and, you
17 know, all the sections that have to do
18 with mesh and slings are in that course.

19 I would ask if you like, if
20 we're going to do that, I would take out
21 the things that have to do with
22 constipation and, you know, things that
23 don't have to do with mesh or slings just
24 so that it's not like this (indicating).

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1 But if you want it all, I'll follow
2 instructions.

3 Q. Right. So, this is not supposed
4 to be a difficult question. I mean, what
5 I'm trying to figure out is what I'm going
6 to see at trial and what you're going to
7 discuss at trial. This is the
8 supplemental reliance list as I know it,
9 and this is what has been provided to us

10 as the things you relied on. And I am not
11 including your experience and learning and
12 knowledge and all those things because I
13 understand there's not a material for
14 that.

15 I'm trying to figure out what
16 materials that I'm going to look at at
17 trial or that you could potentially be
18 using at trial that are not included in
19 your supplemental reliance list or your
20 report.

21 A. I think we can safely say what
22 you have in front of you are the
23 materials, or the scientific materials
24 that are going to come forward.

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1 I cannot separate the literature
2 from opinions I'm going to have based on
3 every other source and way that I learned,
4 that those are not going to be opinions.
5 But from the standpoint of materials, I
6 think you have what I'm going to present
7 to the court.

8 The only clarification I would
9 give there is that these articles in and
10 of themselves have references. So those
11 references I would consider as part of
12 what I might reference. Meaning in the
13 bibliography of an article, it may
14 describe the articles that are support
15 itself, and I may speak to articles that
16 are in the bibliography that are not --
17 that you don't have as a full.

18 Q. So, it's your belief that by
19 closing an article as something you relied
20 on, that you're therefore disclosing, for
21 example if there's a hundred citations for
22 it, you're disclosing all of those?

23 A. Well, if I'm reading a Schimpf
24 article and we're discussing Schimpf and

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1 we're discussing Schimpf which is an
2 article I've disclosed and it is relevant
3 to discussing the data that she disclose,
4 for example the leg pain data, and it's
5 part of my knowledge that the articles

6 that comprise the 16.7 percent have
7 information X, Y and Z, I consider that
8 fair game. If it's not legally, you'll
9 inform me.

10 Q. Okay.

11 So, are you needing to update or
12 supplement your reliance list? Is that
13 what you're telling me?

14 MS. GERSTEL: Objection.

15 THE WITNESS: Am I supposed to
16 answer that?

17 MS. GERSTEL: No, go ahead.

18 A. If I had the opportunity, given
19 that your goal is to have everything that
20 would be presented, I would update it.

21 Q. Can you update this and provide
22 me a final reliance list that will include
23 everything that you intend to rely on?

24 A. I'd be happy to do that. And I

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1 promise that between now and any
2 subsequent time we meet there won't be ten
3 more to add. So I would be happy to, I

4 think, come together on what this
5 discussion's been and if was given the
6 opportunity to update it, I would add
7 about ten articles and we could call that
8 yes, you have in front of you the articles
9 I would rely on.

10 Q. Okay.

11 A. The materials.

12 Q. Well, let's do that because I
13 want a final materials list. So, I mean,
14 that's the goal.

15 A. Okay.

16 MR. DeGREEFF: How soon can we
17 get that?

18 THE WITNESS: In a few days.

19 MS. GERSTEL: Yeah.

20 MR. DeGREEFF: Okay. That's
21 fine.

22 So, I'm going to mark a blank
23 document as Exhibit 9, and then we can
24 provide the supplemental materials

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1 list to the --

2 THE WITNESS: I'm making myself
3 a homework note.

4 MR. DeGREEFF: -- to the court
5 reporter.

6 Sir, for the record, can we
7 agree that you are going to provide
8 what is going to be a final reliance
9 list to your counsel to be provided to
10 me and the court reporter?

11 THE WITNESS: Yes.

12 MR. DeGREEFF: Thank you.

13 And we will mark that as
14 Deposition Exhibit Number 9.

15 (Lind Exhibit 9, placeholder for
16 production by the witness, was marked
17 for identification, as of this date.)

18 BY MR. DeGREEFF:

19 Q. Looking at Exhibit 8, the
20 current version of the supplemental
21 reliance list, that reliance list is more
22 than a hundred pages long.

23 Right?

24 A. I believe you.

1 Q. Is it fair to say it includes
2 thousands of documents and materials?

3 A. Yes.

4 Q. Who chose the documents on that
5 reliance list?

6 A. I chose the vast majority and
7 counsel suggested some additional.

8 Q. You chose the vast majority of
9 the internal Ethicon documents that are on
10 that reliance list?

11 A. No. Of the -- of the scientific
12 literature.

13 I didn't choose any of the
14 Ethicon documents.

15 Q. Okay.

16 So, of the documents on your
17 reliance list, is it fair to say that the
18 portion you provided input on is the
19 medical literature section?

20 A. Yes.

21 Q. And the remainder of it was
22 chosen by defense counsel?

23 A. The -- for the most part, yes.

24 Q. What percentage of the medical

1 literature would you say you chose?

2 A. 75 percent.

3 Q. Who chose the remaining 25
4 percent?

5 A. Counsel.

6 Q. What was the methodology you
7 applied for choosing the medical
8 literature that was included in the
9 reliance list?

10 A. You know, I started -- I like to
11 start on my own. I started on my own
12 doing my Pub Med searches on the different
13 products, then the different products plus
14 complications, and from those choosing
15 articles that I wanted. And when I got to
16 areas where I felt that I was incomplete
17 or didn't really have -- didn't seem to
18 have authoritative understand, I'd say do
19 you have anything on this. Then they
20 would provide materials.

21 So, you know, it was kind of a
22 back-and-forth. It was really -- I was

23 trying to tell my story and when my story
24 had gaps, I said do we have more

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1 information that I'm not finding on this.
2 It's hard when you try to do a -- you
3 know, the limitation where requests were
4 made, it's really just a function of how
5 large the literature is. When you put in
6 midurethral slings, you get 4,000 on Pub
7 Med. So, I was very, very diligent in
8 preparing this report, but when going
9 through 4,000 on a midurethral sling
10 search and, you know, several hundred when
11 you put in a TVT-0 search, a TVT-0
12 complication search, FDA, you know,
13 notifications list, you know, it's just --
14 the reality is unless I had a full-time
15 job, I could review 10,000 documents and
16 figure out which were relevant. So I
17 pulled the ones which clearly looked right
18 to me. I tried to point more towards the
19 randomized controlled trials, that sort of
20 thing.

21 So, I created a story. And when
22 the story had areas where I didn't feel I
23 had good literature, I said do you have
24 articles that I don't in this area and

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1 they -- sometimes they said yes, and
2 sometimes they said no.

3 Q. Did you ever inquire as to
4 defense counsel's methodology for
5 selecting the literature included in the
6 reliance list?

7 A. No.

8 Q. I think you said you spent about
9 40 hours reviewing the materials on the
10 reliance list.

11 Is that correct?

12 A. Right.

13 Q. Fair to say you did not review
14 every document on that 102-page
15 supplemental reliance list?

16 A. I scanned the title of every
17 article and decided which ones I wanted to
18 look into further.

19 Q. Okay. So, fair to say you did
20 not review in detail every piece of
21 medical literature included on that
22 supplemental reliance list?

23 A. That's fair to say.

24 Q. Did you review all of the

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1 nonmedical literature documents?

2 A. I'm not sure which ones you're
3 referring to specifically.

4 Q. Okay. Well, anything that's not
5 designated as medical literature on your
6 report, did you review all of those
7 documents?

8 MS. GERSTEL: Object to form.

9 A. Well, I think I stated
10 previously that I reviewed some Ethicon
11 internal documents and did not review
12 others.

13 Q. So, it's reasonable to say that
14 you didn't review everything on your
15 reliance list.

16 Right?

17 MS. GERSTEL: Object to form.

18 A. I read the titles of each and
19 selected the ones I thought were most
20 pertinent.

21 Q. I'm not talking about just
22 medical literature.

23 I'm saying you didn't review all
24 of the documents on this 102-page reliance

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1 list in 40 hours.

2 Right?

3 A. In detail, no.

4 Q. That would have been essentially
5 impossible?

6 A. Thousands of hours.

7 Q. Right.

8 Would have taken thousands of
9 hours to review all those, right?

10 A. In detail to really read through
11 an article in depth.

12 Q. Because if you've got thousands
13 of documents on your reliance list --

14 A. It's ten minutes per, minimum.

15 Q. Right.

16 So you're looking at 10,000

17 hours to review all those documents.

18 Right?

19 A. Correct.

20 Q. And you essentially did what you

21 could in 40 hours.

22 Right?

23 MS. GERSTEL: Object to form.

24 A. I spent the time I felt

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1 necessary to do an excellent job on -- on

2 the task, understanding that reading every

3 item available on it provided in the world

4 or on the reliance list was not possible.

5 Q. What percentage of the medical

6 literature on your supplemental reliance

7 list did you actually review in detail?

8 MS. GERSTEL: Object to form.

9 A. In detail, I would say 30

10 percent.

11 Q. What percentage of the total

12 documents on the reliance list, all of

13 them including the internal documents and
14 everything else that's on there, did you
15 actually review in detail?

16 MS. GERSTEL: Object to form.

17 A. I can't give you a percentage on
18 it.

19 Q. How did you decide which
20 articles to review in detail and which
21 ones not to?

22 A. The quality level of the study
23 was the primary, meta-analysis, systematic
24 reviews or randomized control trials, and

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1 then of course I was interested on the --
2 I mean, I -- those are all the comparative
3 trials. And then in those comparative
4 trials, I wasn't seeing a lot of themes
5 which I know are being proposed as
6 problems or negative aspects of some of
7 the products. So I looked for -- I did
8 a -- I did a search on complications. So
9 I went through complication articles on my
10 search and decided to pick out ones that I

11 should review that seemed to be at odds
12 with the randomized controlled trials.

13 Q. Did you review all of the
14 articles that were selected and provided
15 by defense counsel?

16 MS. GERSTEL: Object to form.

17 A. I would say I reviewed every
18 title and decided, based on the time frame
19 I had, which ones were relevant and
20 comprehensively reviewed a very good
21 fraction of them, but not all of them.

22 Q. You have on your reliance list
23 17 pages -- excuse me. On your
24 supplemental reliance list 17 pages of

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1 what are referred to as production
2 materials. I think it's around page 75,
3 if that helps.

4 A. In this document?

5 Q. Yes. In Exhibit 8.

6 A. Do you want to show me where
7 that is?

8 Q. I'll try.

9 (Pause.)

10 Q. I'll start over.

11 You have often Exhibit 8, which
12 is the supplemental reliance list that's
13 currently available, 17 pages of what are
14 referred to as production materials.

15 Do you see where I'm at?

16 A. Yep.

17 Q. And that's hundreds of documents
18 listed on there, right?

19 A. Yep.

20 Q. What qualifies as a production
21 material, for purposes of this reliance
22 list?

23 A. I don't know what definition
24 they give to qualify it as a production

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1 document. It's a term you're using that
2 I'm not aware is how it's used for
3 selection.

4 Q. Well, it's not a term I'm using.
5 It's a term that's on the reliance list.

6 A. Where is that term?

7 Q. At the top there (indicating).

8 A. It says "Production Materials."

9 So, let's see what we got here.

10 This would appear to be internal

11 documents describing various aspects of

12 bringing product to study, to develop, to

13 bring forward.

14 Q. Was today the first time you

15 knew there was a heading for production

16 materials on your supplemental reliance

17 list?

18 MS. GERSTEL: Object to form.

19 A. On the heading, I had not seen

20 the heading. I've seen this list of

21 documents, and I've read a good fraction

22 of them.

23 Q. You didn't know there was a

24 heading because you didn't draft it.

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1 Right?

2 MS. GERSTEL: Object to form.

3 A. I didn't know there was a

4 heading because when you turn it over,

5 it's so thick that it's covered by the
6 stapled area.

7 So, in looking over this to look
8 at each number, the heading on the page
9 was not particularly of importance to me
10 when I was reviewing it.

11 Q. I mean, you had seen the
12 supplemental reliance list before today.

13 Right?

14 A. Yes.

15 Q. Was there a staple on the page
16 then?

17 A. There was a clip or a staple or
18 something.

19 Q. Who selected the document --

20 MR. DeGREEFF: Strike that. I
21 think we already talked about this.

22 Q. The documents included in this
23 production materials section were selected
24 by defense counsel.

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1 Correct?

2 A. The internal documents were all

3 selected by counsel.

4 Q. Did you review all of these --

5 MR. DeGREEFF: Strike that.

6 Q. Did you review any of these
7 documents included in the production
8 materials section?

9 A. Yes.

10 Q. What percentage of them?

11 A. 20 percent.

12 Q. And how did you select which
13 documents you reviewed?

14 A. You know, based on what I was
15 reading. I asked for a number of topics.
16 I'd say, you know, tell me, you know, I
17 was particularly interested in discussions
18 of laser-cut mesh. I said are there any
19 internal documents describing concerns
20 about the thigh and the obturator.

21 So, a good fraction of them were
22 things I came upon where I felt like I
23 wanted to know what was going on in the
24 decision-making, and then others were

1 offered by counsel.

2 Q. Well, you didn't select any of
3 the internal documents.

4 Right?

5 MS. GERSTEL: Objection; asked
6 and answered.

7 A. I selected the topic. The
8 information and then the internal document
9 was provided on the several topics that I
10 asked about.

11 Q. Were you given any kind of
12 access to the document production database
13 so that you could do your own search for
14 documents?

15 A. I was given a binder of enormous
16 numbers of company documents, and I
17 discussed that I -- it would be impossible
18 for me to review all of them. So it would
19 have to be a combination of things I was
20 interested in and things that counsel
21 thought was most relevant for us to
22 discuss given reasonable but pretty
23 significant preparation.

24 Q. My question is, I apologize.

1 Were you given access to there's
2 an online database where all of the
3 documents were produced.

4 Were you given access to that
5 online database so you could do your own
6 searches?

7 A. The online database, no.

8 Q. There's around 81 depositions on
9 your reliance list. It's towards the end.
10 It's after the production materials
11 section.

12 So, that is a section on your
13 reliance list that includes about 81
14 depositions.

15 Correct?

16 A. I'll trust your number.

17 Q. Does it look reasonable?

18 A. Yep.

19 Q. Fair to say you didn't read all
20 of those?

21 A. I did not read all of those.

22 Q. Who chose the depositions that
23 were included on this reliance list?

24 A. As stated previously, there are

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1 certain topics I asked for, which would be
2 a smaller subset which -- which I asked
3 for which generated some of these.

4 Now, they probably would have
5 been on the comprehensive list they were
6 planning to include, but I requested,
7 let's say, 10 or 20 documents, or 10 or 20
8 categories of documents and they were
9 provided, and the rest were electively
10 provided by counsel.

11 Q. For example, did you review Meng
12 Chen's depositions?

13 A. I don't recall.

14 Q. Who's Laura Angelini?

15 A. I don't recall.

16 Q. Did you read all of the Piet
17 Hinoul depositions?

18 A. I didn't read all of it. I read
19 some sections.

20 Q. How many of these depositions
21 but actually read?

22 A. I would say I read parts of 10.

23 Q. Which 10?

24 A. Arnaud sounds familiar, Hinoul,

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1 Charlotte Owens sounds familiar, David
2 Robinson.

3 Q. Well, David Robinson sounds
4 familiar because I asked you about the
5 medical director Dr. Robinson earlier.

6 Correct?

7 MS. GERSTEL: Object to form.

8 A. No, I recall independently that
9 that was one of the ones that I had read.

10 Q. How did you select the
11 depositions that you read?

12 A. It would come up in a topic. It
13 would come up in a topic, you know, set up
14 as what was -- what was Ethicon concerned
15 about when they were making the obturator
16 sling, and then some deposition testimony
17 or internal documents were sent on that.

18 What other questions did I ask?

19 I was curious what the, you

20 know, lead directors of the
21 administration's opinions and thought
22 processes were on the topics that are
23 being raised in this litigation. So then
24 some of the directors' transcripts were

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1 provided.

2 Q. So, did you review depositions
3 where Ethicon employees were expressing
4 concerns about making the TVT-0?

5 A. Yes.

6 Q. What were your understanding of
7 the concerns they were expressing?

8 A. They were concerned about groin
9 pain.

10 Q. Anything else they were
11 concerned about?

12 A. There were concerns whether the
13 laser-cut mesh was stiffer and if it was
14 stiffer, if it would change the behavior
15 and/or success or adverse reactions in the
16 procedure.

17 Q. And those were -- those concerns

18 were expressed in the -- by Ethicon
19 employees in the depositions you read?

20 A. I'm mixing together in my mind
21 the depositions versus e-mails. So this
22 is just -- to me it's just in my head as
23 internal documents.

24 Q. Okay.

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1 Did you specifically request by
2 name any of the depositions that are
3 included in the reliance list?

4 A. I requested by topic 'cause I
5 didn't know the names of the players I
6 mean, looking back, I remember interacting
7 with some of these people when I was
8 helping to teach some of their labs and
9 that sort of stuff, so I remember some of
10 the names, but I didn't have any reason to
11 select the names that I knew. There were
12 topics that I was interested in.

13 Q. Then there are six pages of,
14 quote, other materials, right after the
15 depositions.

16 A. Okay.

17 Q. What's included in the other
18 materials section?

19 MS. GERSTEL: Object to form.

20 A. This looks like authoritative
21 articles or materials from authoritative
22 entities, such as FDA, ACOG, AUA, the
23 other quality and research and scientific
24 administrative agencies and female pelvic

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1 medicine.

2 There are some studies, a lot of
3 guidelines, position statements, bulletins
4 by the authoritative societies.

5 Q. Who chose those materials?

6 MS. GERSTEL: Objection.

7 A. Those are mostly by me. I had
8 put them in my report by my own
9 discretion, and I was being followed very
10 closely in our societies the growing,
11 growing support of the midurethral sling
12 based object its data, safety and efficacy
13 profiles. So the -- it was a very strong

14 part of my report was to -- it was a very
15 strong part of my report to -- so, these
16 are mostly requested by me because --
17 either provided by me or requested by me
18 because they came across through my
19 societies with a very, very strong
20 repeated, repeated support for the case
21 for the midurethral sling being important
22 to preserve and important to clarify for
23 the educational world, the patient world.
24 Q. You asked for Dr. Elliott's

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1 curriculum vitae?

2 A. No. Again, if we're going to go
3 item by item, I can tell you whether I
4 requested it. I'm talking about the
5 dominant fraction of these are things that
6 I provided or requested. I did not
7 request all of them.

8 Q. What percentage of them did you
9 request?

10 A. The first page is about half.
11 The second page is a quarter. The third

12 page is a third. The page that's got
13 Daniel Elliott, I would say none.

14 Q. Is it fair to say you requested
15 less than half of the materials included
16 in -- the documents included in the other
17 materials section of your reliance list?

18 MS. GERSTEL: Objecting to the
19 form.

20 A. Somewhere between 30 and 50
21 percent.

22 Q. And what percentage of these
23 materials did you actually review?

24 A. The ones that I requested I

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1 reviewed.

2 Q. And the rest of them were put on
3 the reliance list by defense counsel.

4 Is that correct?

5 A. Yes.

6 Q. For example, there are some
7 things in the other materials that say,
8 for example, excerpts from Budke trial
9 transcript.

10 Who would have done these
11 excerpts? Is that something you did?

12 A. I don't know.

13 Q. Who would have chosen the
14 excerpts that were used?

15 A. I don't have the answer to that.

16 Q. Do you remember reviewing any
17 excerpts from trial transcripts?

18 A. There were one or two trial
19 transcripts which I did review. I can't
20 tell you which ones.

21 Q. So, on the very last page of
22 Exhibit 8, your supplemental reliance
23 list, there's a number of expert reports
24 listed.

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1 Do you see that?

2 A. Got it.

3 Q. Did you review all these expert
4 reports?

5 A. I didn't review all of them, no.

6 Q. Why was it important to you to
7 review expert reports?

8 A. It would educate me on the
9 opinions of the plaintiff experts as to
10 what they felt was most relevant and what
11 the arguments were on the plaintiff's
12 side.

13 Q. And which ones did you review?

14 A. When I was doing my Prolift
15 general report, I read Garely and Elliott.
16 I remember those names. We had one
17 Rosenzweig report because it was
18 associated with one of the case-specific
19 reports. He was the case-specific expert,
20 so I read his report when I read that. So
21 I read three or four.

22 Q. So you read three or four of the
23 maybe 30 or so that are on here?

24 A. Right.

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1 Q. Did the plaintiff's expert
2 reports that you read reference documents
3 that were contrary to your opinions in
4 this case?

5 A. Yes.

6 Q. Are those documents, are they
7 referenced on your reliance list?

8 A. I have a lot of -- I was pretty
9 good on my report about putting in, you
10 know, negative articles that are of
11 question.

12 I would say that there are
13 negative articles in a more comprehensive
14 list on there. They're not all in my
15 report. But I did select articles which I
16 felt were either I found on my own or that
17 I was -- saw were focuses of plaintiff's
18 reports and chose to comment on them.

19 Q. So the plaintiff's experts are
20 medical literature and documents in their
21 reports that were adverse or contrary to
22 your opinions that were not included on
23 your reliance list or in your report.

24 True?

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1 MS. GERSTEL: Object to the
2 form.

3 A. Some are included and some are

4 not included. Correct.

5 Q. Did you review those documents
6 or pieces of medical literature that were
7 contrary to your opinions?

8 A. I read through a good fraction
9 of them on the reports that I read.

10 Q. How did you get the internal
11 documents that they referenced? Did you
12 ask defense counsel for them?

13 A. When I thought it was relevant.

14 Q. Were those documents provided?

15 A. When asked for, yes.

16 Q. Did you pull each of the
17 deposition citations in the plaintiffs'
18 expert reports?

19 MS. GERSTEL: Objection.

20 A. I did not pull every one. I
21 pulled a good fraction of them based on
22 what the title were and the time
23 constraints.

24 So the answer is I did not pull

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1 all of them. I pulled a very good

2 fraction of them.

3 Q. Of the deposition excerpts?

4 A. The depositions, I'm sorry.

5 The expert reports was a good
6 fraction. The deposition excerpts, if
7 there was a reference to an internal -- a
8 few. A few. I can't say that was
9 comprehensive. And the deposition reports
10 at times were so extensive, you know, it
11 could be a week-long deposition that
12 sometimes the purpose of that review was
13 not to comprehensively understand all the
14 depositions that went on. It was to get a
15 flavor for what kind of discussions, you
16 know, the employees, the administrators
17 were having related to the topic, just to
18 get a flavor for what was going on
19 internally there. They're extremely long
20 and not possible to drill down on and
21 examine comprehensively.

22 So I would say on the except
23 reports I pulled a good fraction. On the
24 deposition reports, a very small number.

1 Q. Okay.

2 So, why are there so many
3 documents on your reliance list if you're
4 not relying on them?

5 MS. GERSTEL: Objection to form.

6 A. You know, in discussions, when
7 we bring a topic and, you know, if I say
8 that, you know, I've seen this internal
9 document and I think it's relevant, I'd
10 like to have access to the documents if I
11 choose to review them. So then they are
12 added.

13 So, you know, there are times
14 where I'm in the discovery process and
15 putting together the report process and I
16 say gosh, I see that there's this internal
17 document that talks about X. I say well,
18 I'd like to see internal documents that
19 discuss, you know, A, B, C. So these are
20 added. And then the ones that I see
21 pertinent I review and the ones that just
22 don't make the cut based on trying to do
23 an excellent job, but having a body of
24 literature and internal documents that's,

1 you know, a four-year Ph.D. thesis worth
2 of true deep dive, you have to make your
3 choices.

4 Q. I mean, fair to say you're
5 obviously not relying on them if you
6 haven't reviewed them.

7 Right?

8 MS. GERSTEL: Object to form.

9 A. I am not relying on articles
10 that I haven't reviewed.

11 Of course I would ask the
12 question am I permitted to review those
13 and use them moving forward, but I guess
14 this is really not the place for that
15 question. I'll take that up with counsel.

16 Q. Yeah. I'll let you take that up
17 with her.

18 I want to look at Exhibit 7,
19 which is your report, if you don't mind.

20 A. Sure.

21 Q. On page 15 under complications.

22 Are you following me?

23 A. Mm-hm.

24 Q. There's a section where you say:

202

1 Surgeons should also advise their patients
2 of their own success and complication
3 rates as well as rates that are published
4 in the peer-reviewed literature. In our
5 practice, the complication rates with TVT,
6 TVT-0, TVT-Exact, and TVT-Abbrevio are
7 infrequent and almost without exception
8 complications can be resolved with the
9 patient remaining content and pain free.

10 Did I read that correctly?

11 A. Yes.

12 MS. GERSTEL: I'll just state it
13 was continent, not content.

14 MR. DeGREEFF: Continent.

15 That's a great point. Content is
16 different.

17 BY MR. DeGREEFF:

18 Q. So, is it your intention to give
19 opinions on complication rates with the
20 TVT products in your practice?

21 A. The main thrust of giving
22 opinions on complication rates comes from
23 the enormous data.

24 In my practice, I have not

203

1 collected the patients and organized them
2 in a systematic trial where I have a
3 quantified, reviewed and seen how many
4 come back and systematically recorded
5 their efficacy and safety.

6 It is our routine practice to
7 have them come back at three months, six
8 months, one year and two years and the
9 patients come back in high frequency. Do
10 I know it's 99 percent, do I know it's 90
11 percent? I don't. I know it's a high
12 fraction. I know that the patients are --
13 I know that the complication rates are
14 low.

15 We have a quarterly Pelvic
16 Surgeon Society meeting in Manhattan, and
17 we have an agreement with all the local
18 experts where maintaining patients'

19 confidentiality, we will let each other
20 know if problems and complications have
21 come in that we're not aware about.

22 So, I don't have an organized
23 statistical study to tell you on my
24 patients.

204

1 I will state from my practice of
2 seeing them regularly and insuring that
3 they come back at those intervals, that I
4 feel very confident that my efficacy and
5 safety reflects that of the literature.

6 Q. Okay. So, I think that was a
7 long way of saying, and maybe I'm wrong,
8 but I think it was a long way of saying
9 that you are not going to give opinions
10 regarding your personal complication rates
11 in your practice.

12 A. I don't think that's what I said
13 at all.

14 MS. GERSTEL: Objection.

15 BY MR. DeGREEFF:

16 Q. Okay. Well, how do you track

17 the success and complication rates in your
18 patients? What's your systematic method?

19 MS. GERSTEL: Object to form.

20 A. The patients are not recorded in
21 a long-term spreadsheet with data.

22 My way of tracking complications
23 is making sure they come back and there's
24 a reminder on the electronic medical

205

1 record, if they don't make the
2 appointment, we call them to come back,
3 and we get back well over 90 percent of
4 our surgical patients at a year or two
5 years.

6 So, I know and I see them at one
7 year and two years and I know if they're
8 having problems. So, if I have a -- my
9 own patients and I have 90 to 95 percent
10 of them back and I have to do one mesh
11 exposure, I feel pretty confident that my
12 mesh exposure rate is doing well. It is
13 not statistically quantified, but it is,
14 by virtue of the surveillance in our

15 office, pretty tightly assured that I'm
16 seeing over 90 percent of my patients
17 back.

18 BY MR. DeGREEFF:

19 Q. So, this is essentially
20 anecdotal. You don't have any spreadsheet
21 or statistical analysis or tracking system
22 with regard to complications with mesh
23 patients that you can point me to or show
24 me?

206

1 MS. GERSTEL: Object to form.

2 A. I can point you to the number of
3 cases I've done and the number of mesh
4 erosions that have been revised. I can
5 statistically quantify. I can quantify, I
6 can search for bladder injury and I can
7 quantify that and give it to you over and
8 N, which would be the total number. I can
9 quantify tie prolonged catheterization due
10 to voiding dysfunction. So, these are
11 all --

12 Q. Well, you need a numerator and a

13 denominator, right?

14 A. Mm-hm.

15 Q. How do you track your patients
16 that are lost to follow-up?

17 A. I would have to see if they --
18 on the EMR if they showed up.

19 Q. So, all of this you're talking
20 about is not an analysis that you've done
21 currently.

22 True?

23 A. Correct.

24 Q. You don't have any kind of

207

1 internal registry tracking your patients
2 to see what complications they've had
3 over, say, a five-year period?

4 A. That is correct. The
5 preponderance of my opinion is based on
6 the 4,000 articles on midurethral slings
7 that are published.

8 Q. That's different.

9 You being able to opine about
10 literature is different. I'm asking about

11 your personal complication rates.

12 You have no systematic method in
13 place at your facility for tracking
14 complication rates and those that are lost
15 to follow-up.

16 True?

17 MS. GERSTEL: Object to form.

18 A. I have a systematic method of
19 following up to make sure that over 90
20 percent of my patients return and I know
21 how they're doing. It is not recorded,
22 collected, and it has not been made into a
23 study with a numerator and a denominator.

24 Q. And you haven't tracked patients

208

1 that are lost to follow-up, true? We
2 don't know what their ultimate results
3 were?

4 A. We call all of them back and we
5 get almost all of them back. We get over
6 90 percent of them back. That I know.
7 And most studies of two years don't do
8 better than 90 percent.

9 Q. What I'm hearing you say, and I
10 think what we agree on, is that you have
11 not done any kind of formal analysis and
12 you have no tracking system in place with
13 regard to the complications for your
14 patients related to the TVT products.

15 True?

16 MS. GERSTEL: Object to form.

17 A. I would say I haven't done a
18 formal analysis. I would say I have a
19 tracking system to insure that I'm
20 capturing my patients.

21 Q. And that tracking system is just
22 you know how many of your patients have
23 come back?

24 MS. GERSTEL: Object to form.

209

1 A. Right. And then I know -- and I
2 know on those patients if they have
3 problems.

4 Q. What does the literature say
5 about the average rate of patients that
6 are lost to follow-up?

7 A. It's quite variable.

8 Q. How do you track the
9 complication rates in your patients with
10 regard to specific mesh products?

11 A. Well, I use the same mesh
12 products most commonly.

13 Q. For example, what's your
14 tracking system on the number of TVT-0s
15 that have been implanted and whether they
16 have had complications or not?

17 A. The system would be the same as
18 I recorded -- as I responded before, is I
19 would have the patients back and see how
20 they're doing.

21 Q. Okay.

22 A. It's not systematic, but it's
23 systematic that they come back.

24 Q. How do you track whether the

210

1 mesh implanted in your patients is
2 mechanical or laser cut?

3 MS. GERSTEL: Object to form.

4 A. I know the products I'm using.

5 Q. For example, if you use TVT-0,
6 how do you know whether you've used a
7 mechanical-cut or layers cut TVT-0? How
8 do you track that?

9 A. It's marked on the box.

10 Q. Yeah. But what's your tracking
11 system?

12 A. I don't care which one it is.

13 Q. So there isn't one, right?

14 A. It's not a clinically relevant
15 distinction for me.

16 Q. My question was a little
17 different than that.

18 My question is there is no
19 tracking system in place for your patients
20 with regard to whether there's been
21 mechanical or layers cut mesh used.

22 True?

23 A. True.

24 Q. You implant Ethicon slings as

211

1 part of your practice.

2 Right?

3 A. Yes.

4 Q. How many, let's start with just
5 slings first, how many slings would you
6 say you've implanted since you started
7 using them?

8 MS. GERSTEL: Object to form.

9 A. It's in the 2800 to 3500 range.

10 Q. And we're talking about mesh
11 slings, right?

12 A. Yes.

13 Q. When did you first begin
14 implanting mesh slings in women?

15 A. Well, the TVT we first started
16 implanting in 2000, but we had been doing
17 some patch cut slings with suture before.
18 So there was some modifications. But in
19 terms of the TVT slings and the slings --
20 the midurethral slings that were created
21 to be individual units and made for that
22 purpose, around that time.

23 Q. That was in? I didn't catch the
24 time. Late 90 or 2000?

1 A. 2000.

2 Q. Which of the TVT line of slings
3 have you implanted?

4 A. I have implanted all of them.

5 Q. So you've implanted the TVT?

6 A. Mm-hm.

7 Q. The TVT-0?

8 A. Mm-hm.

9 Q. The TVT-Abbrevio?

10 A. Yes.

11 Q. And the TVT-Exact?

12 A. Yes.

13 Q. Which of those do you currently
14 use?

15 A. I use the TVT-Exact.

16 Q. When did you stop using the TVT?

17 A. I was an avid TVT user, and then
18 I liked the idea of a smaller needle. I
19 thought the procedure could be done with a
20 smaller needle. So I proposed that to
21 Ethicon. They declined that idea. So I
22 proposed it to Boston Scientific and they
23 made the Advantage Fit. So when the
24 Advantage Fit came out and was a very -- I

1 thought very similar in every way with a
2 number of very nice changes that I liked,
3 I switched to the -- staying retropubic, I
4 switched to the Advantage Fit.

5 Q. Okay.

6 And that is a Boston Scientific
7 product?

8 A. Correct. And then --

9 Q. And when did you switch to that
10 from the TVT?

11 A. I don't know exact time. Four
12 years later, five years later.

13 Q. So in 2004, 2005?

14 A. 2005, 2006 range.

15 Q. So you have not used the TVT
16 since 2006?

17 A. I still use the TVT-Exact.

18 Q. Right.

19 But you haven't used the TVT,
20 was my question?

21 A. Correct.

22 Q. And what were the advantages of
23 the -- I guess what was better about the

24 Advantage Fit Boston Scientific sling

214

1 versus the Ethicon TVT?

2 MS. GERSTEL: Object to form.

3 A. I liked that it had blue sleeves
4 over the introducer, which were easier to
5 see in the bladder if you had a bladder
6 perforation. The other color could get
7 lost in the background of the bladder and
8 be missed.

9 I liked that the blue tubes
10 allowed you to twist and untwist the sling
11 so when that it's wrapped around the
12 urethra and there are little tiny twists
13 to it you could align it more perfectly.

14 And I liked that it was 2.3
15 millimeters instead of 5. That was a
16 significantly, significantly different
17 smaller needle.

18 Q. So, the smaller needle was --
19 what's the advantage of the smaller
20 needle?

21 A. It's, you know, it passes

22 through the tissues easier. It makes a
23 smaller puncture in the skin. You need a
24 smaller exit. And it lets you -- again,

215

1 the subtleties of the case require you to
2 move this needle, thread it between the
3 bladder and the pubic bone and when you
4 fail, you get a bladder perforation. So
5 with the smaller needle, I felt, based on
6 the cadaver labs, that you could thread
7 that space a little more easily and then
8 if you do get a puncture in the bladder,
9 you get a 2.3 millimeter puncture instead
10 of a 5. So when you take it out, the
11 bladder constricts at that point and I
12 felt that I did like that -- you know,
13 when you did have a bladder perforation
14 inadvertently, I liked that I went through
15 with a needle that was half the size.

16 Q. And then what is the -- you said
17 that the Advantage Fit, the Boston
18 Scientific product, allowed for better
19 alignment of the sling versus the TVT?

20 A. Well, the data and the results I
21 was having on the TVT and the data I was
22 aware of spoke to the fact that however
23 that kit is made to work, it's working
24 extremely well.

216

1 There are times when you're
2 getting to your final moment when you're
3 going to decide is the sling exactly where
4 I like it fit, how loose is it, how tight
5 is it, how is it lying flat. And there
6 are times where one arm doesn't seem to be
7 perfectly parallel with the other arm.
8 And once you've gone through with the
9 product, if it just has a sheathe on it,
10 you can't rotate it. You can't straighten
11 those out.

12 So this is just a visual, a
13 visual thing that aesthetically looks like
14 if you want a sling to lay around, you'd
15 like it to look like that rather than
16 slightly turned. So those tubes, because
17 they had some memory to them, allowed you

18 to make those turns and adjustment and
19 have the mesh visually appear to be
20 flatter when you pulled it through the
21 canals they seemed a little bit askew.

22 Q. These are the tubes on the
23 Advantage Fit?

24 A. Yes.

217

1 Q. Why is it important for the
2 tensioning to be correct on the sling?

3 A. Well, because every sling --
4 every single sling ends up too loose, just
5 right, or too tight. So you got to use
6 the teaching on had you to do the
7 procedure and to leave it truly tension
8 free to try to get the results that the
9 original procedure was producing.

10 Q. What happens if there's too much
11 tension on a sling?

12 A. In the middle case, the patient
13 would have a little difficulty voiding,
14 need a catheter for a couple of days. In
15 a moderate case she'll need it for a week.

16 And in a more significant case, she's not
17 able to regain normal voiding function and
18 you have to release the sling.

19 Q. And by release it, you mean
20 removal or revision surgery?

21 A. Yes. There are some people who
22 describe in the short-term as putting a
23 obturator in the urethra and pulling
24 downward to loosen it and there's little

218

1 data on that and I don't favor that. But
2 yes, I would generally be talking about
3 revision surgery if they had retention.

4 Q. And these things you liked about
5 the Advantage Fit by Boston Scientific
6 were things that you had brought to
7 Ethicon and they declined to do?

8 A. Only the narrow needle was my
9 idea. The things having to do with the
10 tube were theirs.

11 Q. And the needle was important for
12 reducing the extent of surgical
13 complications.

14 Is that kind of the deal?

15 A. Yeah.

16 Q. Which is a patient safety issue?

17 A. Yes.

18 Q. So, when did you start

19 implanting the TVT-0?

20 A. I started implanting about a
21 year after it was released. 2005, 2006.

22 Q. Did you implant -- I mean, how
23 many TVT-0s would you say you've
24 implanted?

219

1 A. About 150 to 200.

2 Q. At some point, did you stop
3 using the TVT-0?

4 A. I did.

5 Q. When was that?

6 A. We -- we were approached with a
7 problem with cost issues where we had
8 seven or eight doctors and each one
9 wanting three different slings. So the
10 hospital had an inventory which they felt
11 was impossible and they said we need you

12 to get together with your data, individual
13 preferences and options for slings and
14 come up with what you want. And the
15 Caldera, I would seen the Caldera product
16 line and it was very, very favorable in
17 our review. It was favorable because of
18 cost. It was favorable because it comes
19 with one piece of mesh that can affix to
20 reusable instruments that let you do every
21 sling, inside-out sling, outside-in sling,
22 top-down retropubic, bottom-up retropubic,
23 all. At any time in the case you could
24 switch. So it was very flexible in terms

220

1 of what you could use it for. It was
2 quite a bit of a cost and it met many
3 doctors' needs all at once. So we trimmed
4 down our product line and gave up the
5 TVT-0.

6 Q. And when was that?

7 A. I can't tell you exactly. It
8 was -- I don't know exactly.

9 Q. Last five years? Last ten

10 years?

11 A. I would say five years ago to
12 six years ago.

13 Q. Did you compare the Caldera to
14 the -- the Caldera is a sling.

15 Correct?

16 A. Yes.

17 Q. And was it the Desara that you
18 chose?

19 A. Yes.

20 Q. And is it -- did you, before
21 choosing it and eliminating the TVT-0 at
22 your hospital, did you look into the
23 safety and efficacy comparison at all?

24 A. We used it in a lab about 20

221

1 times and looked at it in the hand and
2 looked at biochemical properties an
3 determined it was not the same, but very
4 similar.

5 At that point when Caldera had
6 come out, we really had data from most of
7 the sling products that they were

8 relatively equivalent in efficacy and
9 safety.

10 In answer to your question, they
11 did not have significant data on it, no.

12 Q. When did you start using the
13 TVT-Abbrevio?

14 A. You know, when it came out, the
15 concept was appealing and I would
16 alternate between my slings, giving it a
17 try. I used it probably 30 or 40 times.
18 I thought it was a very nice sling. I
19 thought I was -- with my other obturator
20 slings, I wasn't having groin pain. So I
21 kind of thought to myself we have some
22 data on Abbrevio. It's clearly not going
23 through all the same tissues. So we have
24 the potential advantage that it's not

222

1 going all the way through the muscles, so
2 maybe it's leg groin pain. So how well is
3 it anchored.

4 We did have some studies to show
5 relevant equivalency to full-length

6 obturator slings, but I felt that from
7 doing obturator slings and not having
8 groin pain other than from the first week
9 or two, I felt more secure having a
10 full-length sling. So I just decided
11 mostly to stay with that.

12 I do occasionally order it just
13 for the sake of fellow teaching to show
14 the variety of the sling.

15 Q. The TVT-Abbrevio is not a
16 full-length sling.

17 Correct?

18 MS. GERSTEL: Object to the
19 form.

20 A. Correct.

21 Q. How long is the TVT-Abbrevio?

22 A. I don't know the exact length.
23 I'd guess at 12 or 15, but I don't know
24 the exact length.

223

1 Q. I think your report does much I
2 think it's 12 centimeters according to
3 your report.

4 A. Yeah, that's what I recall.

5 Q. Does that sound accurate?

6 A. Sounds about right.

7 Q. What is the length of a
8 full-length TVT sling?

9 A. I think it's in the 23 to 25.
10 Somewhere in that range.

11 Q. And what was the length of the
12 TVT-S, the mini sling?

13 MS. GERSTEL: Objection.

14 A. That, I don't know. That was
15 shorter. I didn't use many of those.

16 Q. Fair to say that the TVT-Abbrevio
17 is closer in length to the TVT-S mini
18 sling than it is to the full-length TVTs?

19 MS. GERSTEL: Objection.

20 A. I'd have to put the numbers on
21 paper, but I don't think the size
22 comparison is the relevant issue.

23 Q. Yeah, that wasn't my question.

24 My question is is it fair to say

224

1 that the TVT-Abbrevio is closer in length

2 to the TVT-S mini sling than it is to the
3 TVT full-length slings?

4 MS. GERSTEL: Objection.

5 A. I would actually say no, I
6 disagree with that because let me -- I
7 will say out of the box the answer is yes,
8 but when you talk about the full-length
9 TVT is meant to be very, very long so that
10 if you have an obese patient, the mesh can
11 emerge from the abdominal wall which has
12 very variable size. So when you talk
13 about how much is cut off and how much is
14 left in the body, I would suggest that the
15 length of the mini TVT or the TVT Secure,
16 which is going to the undersurface of the
17 pubic bone where it's at a junction with
18 the obturator muscle and the TVT-Abbrevio
19 is going to perforate the muscle, those
20 are, you know, a centimeter apart.

21 In terms of the part that's left
22 in the patient, I think they're probably
23 pretty similar.

24 Q. When did you start using the

1 Abbrevio?

2 A. 2006.

3 Q. When did you stop?

4 A. 2010.

5 These are approximates.

6 Q. Yeah, sure.

7 You said you were more
8 comfortable using a full-length sling.

9 Why is that?

10 A. To be clear, my vast
11 preponderance of slings are retropubic,
12 and the reason for that is I started using
13 it in 2000. I had 600, 800 cases done
14 before any obturator sling came out. I
15 was thrilled with my results. I went from
16 doing a Burch with a full incision with an
17 open laparotomy to a the TVT sling, which
18 was 15 minutes. I was not hitting the
19 bladder 'cause my skills are good. I was
20 getting extremely low complication rates.
21 So I had something that the patients
22 were -- had very fast recovery. Took me
23 15 minutes to do. And when the obturator
24 came out, I said to myself that's pretty

1 cool. That's very interesting. I'm going
2 to select my patients to do that when I
3 have anatomy that gives me a reason not to
4 do the one I like because the one I like
5 it would be hard for me in my personal
6 experience to improve upon it because 15
7 minutes, loving my results and almost
8 complication free, no reason to change.

9 So, I used my -- mostly did my
10 obturator slings when someone had a
11 heroin, had a previous hernia repair, they
12 had a previous retropubic surgery like a
13 Burch or a Marshall-Marchetti, abdominal
14 wall surgery with mesh, reasons to stay
15 away from the target zone for the
16 retropubic regular TVT.

17 Q. Again, I appreciate that. My
18 question was different though.

19 My question was your testimony
20 earlier was that you felt more comfortable
21 with a full-length sling.

22 Why would you prefer a

23 full-length sling over a shorter sling?

24 MS. GERSTEL: Object to form.

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1 A. Well, in the case of the
2 retropubic -- are we talking obturator or
3 retropubic or just across the board? Do
4 you want to break it down?

5 Q. I'm talking about the
6 TVT-Abbrevio.

7 A. The Abbrevio.

8 So, I wasn't having any
9 significant groin pain past the immediate
10 perioperative period with the full-length
11 sling. So, since I wasn't having problems
12 with the potential problem with the
13 full-length sling, the only reason to go
14 to Abbrevio is that you're concerned with
15 groin pain or you're having groin pain and
16 you want to see if you can reduce that by
17 having a thread going through instead of a
18 piece of mesh.

19 So, since I wasn't having the
20 pain that would lead you to Abbrevio, I

21 said to myself I have some studies, but
22 they're very early studies and few about
23 the Abbrevio. Does it hold as well. So I
24 said the Abbrevio is not going through all

228

1 the anchoring tissues. So, since I'm not
2 having groin problems, I'll stay with the
3 full-length sling because I don't feel I
4 need to move away from a groin pain
5 problem because I wasn't having it.

6 Q. Okay.

7 Yet the TVT-Abbrevio was brought
8 up by Ethicon in response -- it was
9 supposed to reduce the groin pain
10 associated with the TVT-0 and other
11 obturator devices.

12 True?

13 A. Yes.

14 THE WITNESS: I'm going to take
15 a break just for the bathroom, if I
16 may.

17 (Recess taken.)

18 BY MR. DeGREEFF:

19 Q. When did you begin using the
20 TVT-Exact?

21 A. When it came out, I was using
22 Caldera and I was using the Advantage Fit.
23 So I mixed it in for teaching purposes. I
24 liked the idea that I was getting the

229

1 Ethicon product back because, you know, it
2 owned the data. So now we kind of took
3 the things that Advantage Fit had kind of
4 changed that I liked. I really liked the
5 slimmer needle for my, again, teaching
6 situation, residents and fellows. So now
7 I had the original with a slimmer needle
8 and with tubes. So that we kind of
9 brought back the two things. So I started
10 using that a bit more frequently.

11 Q. And you started that when?

12 A. Pretty soon after it came out.
13 I usually -- most things I'm the kind of
14 person that says let my other expert
15 buddies get 50, 70 cases done and make
16 sure everybody's having a nice time with

17 it and then I join in.

18 Q. And how many have you put in at
19 this point, do you think?

20 A. Three hundred.

21 Q. And how many, I never asked you,
22 how many of the original TVT did you put
23 in?

24 A. That was before there was a

230

1 competitor. So like ten to -- like 500 to
2 600.

3 Q. The TVT and the TVT-Exact are
4 placed by retropubic approach.

5 Correct?

6 A. Yes.

7 Q. And the TVT-0 and the TVT-A were
8 transobturator approach?

9 A. Yes.

10 Q. I can we may have talked about
11 this already, but it's all a blur because
12 it's been four hours.

13 The transobturator approach has
14 a higher re-operation rate.

15 Correct?

16 A. Yes.

17 Q. It's understood typically that
18 the slings placed using the transobturator
19 approach are less durable than those using
20 the retropubic.

21 True?

22 MS. GERSTEL: Object to the
23 form.

24 A. The data's mixed on that. There

231

1 are RCTUs that show them to have equal
2 efficacy at two and five years and there
3 are RCTs that show somber durability of
4 the TVT-0 over time. That's as I recall
5 the literature.

6 Q. Of the greater durability of the
7 retropubic over time?

8 A. Right. But that's not the
9 dominance of the data. The preponderance
10 of the data shows relatively equivalent
11 rates and Ford and Cochrane's analysis
12 shows that.

13 Q. So the data shows that the
14 devices placed via the retropubic approach
15 are equally or more durable than those
16 placed via the transobturator.

17 Correct?

18 A. Yes.

19 Q. Are you aware of studies finding
20 the rate of re-operation twice as high
21 with the transobturator approach?

22 MS. GERSTEL: Objection; asked
23 and answered.

24 A. I am aware that there are

232

1 studies showing that. I don't believe
2 that that is the collective data of all
3 the meta-analysis, but there are studies
4 that do show that.

5 Q. Okay.

6 When you were implanting the
7 TVT-0 and the TVT-Abbrevio, did you advise
8 your patients that there was a potential
9 increased risk with the obturator
10 approach?

11 MS. GERSTEL: Object to form.

12 A. I advised them of both
13 techniques and I advised them of
14 advantages and disadvantages of both. So
15 I did include the proposed advantages of
16 the TVT-0, and I did tell them the
17 proposed adverse reactions associated with
18 each, because they have a little different
19 profile, each of the slings.

20 Q. What were the differences in
21 potential adverse events between the TVT
22 appeared the TVT-0?

23 A. Southbound the TVT has a higher
24 incidence of organ injury, bladder injury

233

1 and voiding dysfunction.

2 The TVT-0 has a higher incidence
3 of vaginal sulcus perforation, sometimes
4 called an angle needle introduction, groin
5 pain, I would usually describe to them as
6 typically transient and in rare cases
7 prolonged and with those being the major
8 differences.

9 Q. Was the major reason for those
10 deferences the retropubic versus the
11 transobturator approach for placement?

12 A. It was the anatomic pathway?

13 Q. Would the problems associated --
14 that you would have told your --

15 MR. DeGREEFF: Strike that.

16 Q. Would the differences from an
17 adverse event standpoint between the TVT
18 and the TVT-Abbrevio have been similar to
19 the ones we just discussed?

20 A. I think they would be similar,
21 but I think the data bears out, and it
22 makes sense, that you would have a
23 somewhat lesser chance of having groin
24 pain.

234

1 Q. Do you consent the patients to
2 the implant procedure prior to implanting
3 mesh slings into object to form?

4 A. Hundred percent.

5 MR. DeGREEFF: What's the
6 objection?

7 MS. GERSTEL: I'm sorry?

8 MR. DeGREEFF: What's the
9 objection?

10 MS. GERSTEL: You said do you
11 consent patient to the implant
12 procedure. I'm a little confused by
13 exactly what you mean by that.

14 But my objection's on the
15 record.

16 BY MR. DeGREEFF:

17 Q. As part of your consent process,
18 you explain to them the risks and
19 complications that Ethicon mesh slings can
20 cause?

21 A. Yes.

22 Q. What risks and complications do
23 you tell them are associated with the
24 TVT-0?

235

1 A. The TVT-0, I tell them you can
2 have bleeding. You can have pain. You
3 can have dyspareunia. You can have groin
4 pain that is usually transient, but can in

5 some cases be longer standing and require
6 revision. You could require revision for
7 a failure of the procedure, for the
8 procedure being too tight. I inform them
9 of the chance of exposure-slash-erosion.
10 I tell them there's a chance of voiding
11 dysfunction. There's a chance of puncture
12 of the urethra or the bladder.

13 Q. Those are all complication that
14 is could be caused by the TVT-0 mesh
15 sling.

16 True?

17 A. Yes.

18 Q. When you advise them about pain,
19 do you advise them about the potential for
20 chronic pain?

21 A. I tell them there's a potential,
22 but it's rare.

23 Q. And what about dyspareunia, do
24 you advise them of the potential for

236

1 chronic and ongoing dyspareunia?

2 A. I do.

3 Q. Exposure and erosion, what is
4 exposure and erosion?

5 A. Well, you could probably ask ten
6 experts and get ten different answers, but
7 I would put it this way.

8 Exposure, literally the
9 definition of the word means you can see
10 the mesh. So, let's say the wound is open
11 somewhere. How it got opened we're not
12 talking about, but you can see the mesh.

13 In erosion you're also seeing
14 mesh. And I would say the distinction I
15 make when you try to think of
16 pathophysiology is that when you do a
17 vaginal procedure, you make a single
18 incision through a very thin tissue. As
19 opposed to the belly where you go through
20 three or four layers. So it is a
21 dependent position and you cannot put a
22 wound dressing on it to support it like
23 you do elsewhere. So it is vulnerable to
24 fluid collecting.

1 I'll try to speed this up.

2 A wound can open and if a wound
3 opens and you have a wound failure because
4 your enclosure wasn't good or you had some
5 fluid collection, the wound opens. Then
6 you'll have an exposure. To me that
7 usually looks like the -- the wound looks
8 innocent. It doesn't show signs of
9 inflammation, of an active process. It
10 just looks like a wound that's separated.

11 When I think of erosion, I think
12 of a more active process. The body didn't
13 like the material that was in there or it
14 got infected. There's a reaction going on
15 and the tissue looks much different. It
16 looks inflamed. It looks like it's
17 pushing it out as opposed to the walls of
18 the wounds that opened and the exposure
19 that's just kind of dangling there free.
20 And in an erosion everything there seems
21 to be more of an active process.

22 So, I don't think there's a
23 strict scientific or medical definition of
24 it. I try to look at it this way and

1 that's from the vaginal exposure.

2 In terms of an erosion into the
3 urethra or into the bladder, you know,
4 those are even tougher because, you know,
5 in the case I described to you, you can
6 just have a wound that opens. So
7 hypothetically, on an erosion to an
8 internal organ, the mesh is moving from
9 one place to another. It was my strong
10 belief that most erosions to internal
11 organs were there when the patient left
12 the operating room.

13 Q. Mesh can lead to mesh erosion.
14 True?

15 MS. GERSTEL: Object to form.

16 A. I would say that I've never seen
17 a mesh placed flight place lead to erosion
18 if erosion is an active process.

19 Q. You can't have mesh erosion or
20 mesh exposure without mesh.

21 Fair?

22 A. Right. Correct.

23 Q. And transvaginal mesh can cause

24 foreign body reaction, right? Like we

239

1 talked about earlier.

2 A. Yes.

3 Q. And that can cause inflammation?

4 A. Yes, it can.

5 Q. And that can cause chronic pain?

6 A. It can.

7 Q. Are the complications that you
8 tell your patients are associated or
9 caused by the TVT-Abbrevio similar to what
10 you advise them on the TVT-0?

11 A. I explain to them the
12 difference. I explain that they have a
13 light -- a likelihood, but not -- of less
14 chance of having groin pain, but not no
15 chance.

16 Q. But other than groin pain, would
17 the other complications that we talked
18 about being caused by the TVT-0 remain the
19 same for the TVT-Abbrevio?

20 A. Yes.

21 Q. I'm just trying to make it so

22 you don't have to go through them all
23 again.

24 With regard to the TVT-Exact,

240

1 how would the -- when you -- the
2 complications that you tell your patients
3 are caused by the TVT-Exact, how would
4 that be different than the TVT-0?

5 A. I tell them they're very
6 similar. I say this is an evolution of a
7 device and this one is a little bit
8 slimmer. Other than it being slim E it's
9 the exact same procedure. I feel in my
10 hands that it lets me go through the
11 spaces a little more easier, and if there
12 is an inadvertent puncture of the bladder,
13 which does happen in a few percentage
14 cases, I like the fact that the hole is
15 smaller and it heals spontaneously.

16 Q. Other than those differences,
17 would the complications caused by the
18 TVT-Exact that you consent your patients
19 to be the same as what we discussed with

20 the TVT-0?

21 A. Yes.

22 Q. And the things we've discussed,
23 these complications we've discussed with
24 regard to that you consent your patients

241

1 on for the TVT products, those are things
2 that are not good for the patients.

3 Right?

4 MS. GERSTEL: Object to form.

5 A. Well, when I'm consenting them
6 and telling them a list of adverse
7 reactions, by definition adverse reactions
8 are not good for the patients, but they're
9 a known risk and they're part of risk
10 benefits of trying to get the benefit of
11 being dry.

12 Q. As part of your practice, you
13 treat women suffering from complications
14 caused by mesh slings.

15 Right?

16 A. I do.

17 Q. In fact, you're at a tertiary

18 care hospital.

19 Right?

20 A. Yes.

21 Q. And you're actually referred
22 mesh complications from other places in
23 the State of New York.

24 Right?

242

1 A. I am.

2 Q. Are there any other states other
3 than New York that you receive referrals
4 of women suffering from mesh complications
5 from?

6 A. 1996 I -- well, before the
7 mesh -- you still had other meshes then,
8 but, you know, 96 to 2005 I was one of
9 like five people in the area. So I had
10 people from multiple, multiple states. So
11 now we've got good trained people in a lot
12 of places, so they come from far less
13 often, but I still will get people from
14 New Jersey, Pennsylvania, Upstate New
15 York.

16 Q. Okay.

17 There are doctors in referral
18 centers like yours for women suffering
19 from mesh complications in states all over
20 the United States.

21 Correct?

22 A. There are many now, yes.

23 Q. And how many referrals a year do
24 you receive from women suffering from mesh

243

1 complications?

2 A. It's decreased quite a bit over
3 the last five years. I think over the
4 last five years the people knowing how to
5 do them right are doing them more often
6 and people who is techniques perhaps
7 weren't as good are doing them less often.

8 So I would say right now I get
9 between five and ten a year.

10 Q. Do you know what mesh products
11 have been pulled off the market in the
12 last five years?

13 MS. GERSTEL: Object to form.

14 A. I might not be able to name them
15 all, but I know a lot of them.

16 Q. Do you think that has anything
17 to do with the decrease in the number of
18 women you're seeing with mesh
19 complications?

20 A. No.
21 Pardon me. Referring to
22 decrease you're referring to slings or
23 vaginal mesh or both?

24 Q. I'm referring, in that question,

244

1 I was referring to transvaginal mesh,
2 period.

3 A. So, then, no. I would correct
4 my answer. I'm sorry.

5 Yes, I think with the removal
6 and direction not to use those products
7 and taken off, it's decreased the access.

8 And I certainly wish they'd do
9 that to the machine guns that have been
10 going off in the last couple of weeks.

11 Q. What complications caused by

12 mesh slings do you treat in your practice?

13 A. Retention, obstruction,
14 exposure-slash-erosion, dyspareunia. I'm
15 not seeing a lot of groin pain.
16 Occasionally urethral erosion.

17 Q. How about chronic UTI?

18 A. The chronic UTI is a tough one
19 when you have to try to attribute it to
20 mesh. When you see patients that have
21 slings in place that have chronic UTI.
22 So, if you have something related to the
23 mesh that explains it, so they're
24 retaining urine and they're not emptying

245

1 and the natural flow process and cleansing
2 process isn't working, you know, you say
3 releasing this would probably help.

4 It's sometimes hard when you get
5 a patient who has chronic UTIs and there's
6 no obstruction. They empty well. The
7 cystoscopy's clear. There's no exposure.
8 They're not behave inflamed or infected.
9 So it's hard. Sometimes we have to make

10 decisions that we don't see something that
11 would make sense that it would be from the
12 sling and you have to judge that.

13 So when there's an obstruction
14 an retention, makes sense. Obviously when
15 there's a piece of mesh in the bladder,
16 makes sense.

17 We do have situations where
18 patient comes in and says I have
19 infections. Is this from my mesh. And we
20 do our assessment and I don't find
21 something that logically attributes to it
22 and you have to decide what to do with it.

23 Q. Have you seen pieces of mesh in
24 the bladder?

246

1 A. Yes.

2 Q. How about inflammation, you
3 treat women suffering from inflammation
4 from mesh?

5 A. Whether the patients come with,
6 like I said, exposure, erosion, most of
7 them are quiet exposure. They notice it

8 because either they felt it when they were
9 touching themselves or the partner felt
10 it. Most of the time mesh exposure is
11 found innocently. They didn't know it was
12 there.

13 When you talk about
14 inflammation, I would say in a small
15 fraction of the exposure-slash-erosions
16 they come in and it seems hotter. That's
17 the one I would say where I was speaking
18 before I'd say this seems to be more of a
19 this one's being extruded because it seems
20 like an active process and they're
21 sensitive and inflamed. But that's a
22 minority.

23 Q. But I think the answer is yes,
24 you do treat women that have inflammation

247

1 caused by mesh?

2 A. Yes.

3 Q. Do you perform surgery to treat
4 transvaginal mesh complications?

5 A. Yes.

6 Q. How about treatment of
7 transvaginal mesh complications caused by
8 mesh slings?

9 MS. GERSTEL: Object to form.

10 A. Yes.

11 Q. What kind of surgeries do you
12 perform?

13 A. If they're too tight, I loosen
14 them. If they're in the bladder, we take
15 it out of the bladder and repair the
16 bladder. If it's in the sulcus and it's
17 uncomfortable with vaginal pain, we have
18 to refresh the sulcus and sometimes the --
19 you might be through into the vagina and
20 sometimes it might be behind the vagina.
21 So not a true exposure, but as
22 uncomfortable. So sometimes we have to
23 release the side band. I've had to do one
24 groin exploration.

248

1 Q. What do you mean by groin
2 exploration?

3 A. An obturator sling who had

4 discomfort by the groin that it was
5 persistent.

6 Q. Have you done removals or
7 revisions related to the TVT mesh
8 products?

9 A. The retropubic?

10 Q. Any of the products in the line.

11 A. Yes.

12 Q. How many?

13 A. 20 to 30.

14 Q. Mesh slings, generally speaking,
15 how many removal or revision surgeries do
16 you think you've done?

17 A. In total?

18 Q. Yes.

19 A. I haven't quantified it. It's
20 five it ten a year now. It was ten a year
21 earlier.

22 I would say hundred to 150.

23 Q. So, you currently do five to ten
24 mesh sling removals per year?

249

1 A. Some kind of revision.

2 Q. What are typically the
3 indications for revision of the TVT mesh
4 sling products?

5 A. The number one indication truly
6 is that their doctor saw it and told them
7 that your mesh is exposed, you should have
8 it taken out. So they come asymptomatic
9 and worried about their mesh. So we have
10 a chat about if you're okay and you're
11 fine and you're in the having any
12 symptoms, you don't have to do anything
13 about it. Half of those patients will say
14 let's get it out, I don't want it there.
15 And half will say hey, if I'm feeling
16 great, let's leave it.

17 So, the most common indication
18 is referred from a physician for something
19 they didn't know about 'cause they -- the
20 physician -- their primary care OB-GYN saw
21 an exposure.

22 Q. So the most common is they're
23 referred for mesh exposure?

24 A. Yeah.

1 Q. And what other indications lead
2 to removal of the TVT mesh slings?

3 A. They have pain or dyspareunia or
4 the partner felt something.

5 Q. And you've revised TVT mesh
6 slings based on all of those indications.
7 True?

8 A. I wouldn't be able to say for
9 every single one of those indications,
10 there was a TVT product. That's -- that's
11 too exact to say that for every one of
12 those it was a TVT. You know, they come
13 and sometimes we could have the op report,
14 sometimes we don't. Sometimes we know
15 exactly which sling it was; times we
16 don't. We do our best to get operative
17 reports. Sometimes we get them; sometimes
18 we can't. Sometimes they've had stuff
19 done in another country.

20 Q. These would all be examples of
21 reasons you've revised mesh slings.

22 True?

23 A. Yes.

24 Q. What percentage of your practice

1 is related to treating transvaginal mesh
2 complications?

3 MS. GERSTEL: Object to the
4 form.

5 Is that all transvaginal mesh?

6 MR. DeGREEFF: Right.

7 MS. GERSTEL: I'll just object
8 to the extent it's outside the scope
9 of this deposition.

10 A. I'd see about 200 a month. I'll
11 see one every other month. One out of 300
12 to four hundred. It's pretty low.

13 Q. That's related to transvaginal
14 mesh complications generally speaking?

15 A. Yeah.

16 Q. Have you ever treated a patient
17 with mesh that --

18 MR. DeGREEFF: Strike that.

19 Q. Have you ever -- well, yeah.

20 Have you ever seen a patient
21 with mesh that is roped, curled, frayed,
22 deformed, folded or wrinkled?

23 A. I've never witnessed those
24 things.

252

1 Q. Do you agree that those things
2 increase the risk of pain for a woman?

3 A. I don't know that those have
4 been assessed in the patient in a study.
5 These all seem to be things of excised
6 mesh and I think the mesh sits differently
7 in the body when it's excised. So I don't
8 see it roped and curled and all of that.
9 It takes the shape of the tissue it's in.

10 Q. So you've never seen or never
11 treated a patient that had mesh that was
12 deformed?

13 A. How do you define deformed?

14 Q. How do you define deformed?
15 You're the doctor.

16 A. I will say on some prolapse
17 cases, if you have a piece of mesh that's
18 attached and the attachment released, so
19 if the procedure fails, then the -- then
20 the mesh will come upon itself and have

21 some folding. I've seen folding on a mesh
22 failure because the attachment points have
23 released, but I don't see curling and
24 roping and what those things are that are

253

1 described. I don't see them.

2 Q. You've never seen any of those
3 with regard to mesh slings?

4 A. I've seen mesh folded on itself
5 when there was a prolapse failure. So the
6 mesh that was attached got released and it
7 came back upon itself and folded.

8 Q. I'm talking about mesh slings
9 now.

10 You're never seen a mesh sling
11 that was roped or curled or frayed or
12 anything?

13 A. I don't know if you consider
14 roping. When a sling is tight and you're
15 going to release it, when you say that
16 patient and it's tight and you go and look
17 at -- and you release it, it looks a
18 little narrower. I don't know if that's

19 roping or curling. It does look a little
20 narrower when it -- when it -- when the
21 tissue contracts and the sling contract
22 with it or whatever reason for that
23 patient and the small fraction that end up
24 too tight and you have to go back, it

254

1 looks a little slimmer.

2 Q. Well, that's contraction of the
3 mesh.

4 Correct?

5 A. I don't know that it's
6 contracture. The mesh looks smaller.

7 Q. So you're saying when it
8 contracts and it gets under greater
9 tension, it looks thinner?

10 A. I don't know if it's an
11 inflammatory response that encases it. I
12 don't know if it's a tissue response. I
13 don't think we have studied that. And to
14 know what I'm referring to what's
15 happening at that point. It just looks a
16 little slimmer.

17 Q. But you've seen mesh slings that
18 have changed shape, that look slimmer.

19 True?

20 A. When I take out patients that
21 have obstructions, they look a little
22 slimmer under the urethra.

23 Q. In your experience removing the
24 TVT products, were you able to remove all

255

1 of the mesh?

2 A. There are times where you decide
3 that you need to remove all the mesh and
4 times when you decide you don't need to.

5 When I decide a patient needs it
6 to be removed, I have removed all of it.

7 Q. You agree that physicians are
8 often unable to remove all the mesh?

9 A. It depends on their training.
10 The patient having a revision is best off
11 with someone with extensive experience in
12 handling this.

13 Q. Well, there are times when it's
14 just not -- when you're just not able to

15 remove all of the mesh.

16 True?

17 A. I have never had a case where I
18 couldn't remove the sling in totality when
19 I needed to.

20 Q. It is challenging to remove all
21 of the mesh from a woman who's suffering
22 complications.

23 Is that a true statement?

24 A. There's some dissections that

256

1 are more difficult than others, but I
2 don't consider it to be an extremely
3 difficult procedure.

4 Q. For example, you know that
5 there's -- with the TVT-0 product, you can
6 never safely removal all of the mesh from
7 inside a woman once it's implanted.

8 Right?

9 A. I agree.

10 Q. Okay.

11 A. The problem you're having and to
12 clarify that disagreement is that there

13 are surgeons who are taking out mesh and
14 they really only have the training to take
15 it out from the middle of the vagina as
16 far out laterally as they can reach and
17 then there are surgeons who know how to
18 get behind the pubic bone and get what's
19 behind the pubic bone and get what's
20 wrapping around the descending pubic
21 ramus. I've had obturators that were
22 taken out in totality several times.

23 Q. You had some that you couldn't
24 take out in totality?

257

1 A. No.

2 Q. Okay.

3 A. Now, microscopically, do I know
4 that there's nothing there, it seemed to
5 us that there was nothing more there. A
6 continuous band of ribbon.

7 Q. Doctor, have you ever been
8 employed by a medical device company?

9 A. As a consultant, not on a
10 payroll.

11 Q. I understand the consultant.

12 I'm saying have you ever been an
13 actual employee of a medical device
14 company?

15 A. No.

16 Q. You have been a consultant for a
17 medical device company.

18 Correct?

19 A. Yes.

20 Q. Which ones?

21 A. The Laurus Corporation, Boston
22 Scientific, Ethicon, Caldera.

23 Q. What about Asera?

24 A. No.

258

1 Q. You've never been a consultant
2 for Asera?

3 A. When AMS was around, I had a
4 couple, very few. So very briefly you
5 could add it to the list, American Medical
6 Systems.

7 Asera, no.

8 Q. Okay.

9 A. Do they go by another name?

10 Q. Not that I know of.

11 A. No.

12 Q. When did you start working for
13 Caldera? I guess start consulting for
14 Caldera?

15 A. About five, six years ago.

16 Q. So 2013, 2014? Something like
17 that?

18 A. About that.

19 Q. What did Caldera have you doing?

20 A. Well, as I said, we got involved
21 in them first in a non- -- I got involved
22 with them first in a non-consulting way.
23 I liked their set of mesh kits, their
24 ability to do everything in one kit, less

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1 expense and flexibility of the kit. So
2 they're a small company and he said, you
3 know, I like to do design innovation. Can
4 we take a look at your products and talk
5 about what can be improved.

6 So, if you take a look -- not

7 that you would take a look to do their
8 history, you'll see that Caldera now has a
9 blue sheathe covered narrow sling, which
10 was my original wish back with Gynecare
11 and Boston Scientific. We -- they wanted
12 to be also involved in the abdominal sack
13 correctly suspension market. We talked
14 about the weight and veracity of their
15 mesh and how it handled and how it might
16 be marked and colored and helped them
17 develop the mesh for sacral suspension.

18 We talked about what's unique
19 about their trocar delivery flexibility
20 and what could be added to that to
21 continue to improve the flexibility
22 options for patients. For instance, took
23 the obturator trocars and said, you know,
24 every woman's not the same size. Let's

260

1 make different sizes. So there are some
2 measurements we can use different sizes.

3 So we've done a lot of different
4 things that are tweaking things. Some

5 have been adopted. Some are in the
6 thought process. Some have been rejected.

7 Q. So, were you essentially -- were
8 you helping them with product design, or
9 were you helping them with research and
10 development?

11 I mean, do you know how were you
12 classified there?

13 A. It really is research and
14 development. It's trying to decide on new
15 products and how to alter products to
16 improve them.

17 Q. Were you working on sling
18 products?

19 A. Sling and mesh products for
20 sacral suspension.

21 Q. And what were your -- what did
22 you tell them about the weight of their
23 mesh? You mentioned that as one of the
24 things you were talking to them about.

261

1 A. I said there seems to be, you
2 know, across the slings -- across the very

3 popular area of abdominal sacral
4 suspensions is a huge broad area of stuff
5 that's really, really lithe, that I
6 thought was too lithe to things that were
7 really stiff and I thought their mesh
8 handled well and was within the realm of
9 acceptable weight and handling and I liked
10 it.

11 MS. GERSTEL: Could I just note
12 for the record I don't know the extent
13 to which any work that Dr. Lind did
14 with any company is confidential.
15 He's obviously taken on oath to tell
16 truth. I don't think I'm in a
17 position to direct him not to answer
18 any of those questions, but I also
19 don't know if we might need to seek
20 that some of this testimony be kept
21 confidential.

22 I just want to say that for the
23 record. I'm just not sure. I just
24 want to state for the record I might

1 need to explore that after this
2 deposition. I'm not going to direct
3 him not to answer the question.

4 MR. DeGREEFF: I mean, if you
5 want to move to have it sealed or
6 something. We may agree to that. I
7 just don't know what it is. If
8 there's some reason for that, then
9 yeah, we can talk about it.

10 MS. GERSTEL: All right.

11 BY MR. DeGREEFF:

12 Q. So, what were the improvements
13 that you suggested to slings?

14 A. For Caldera?

15 Q. Yeah. I mean, you told me that
16 you were looking at ways to improve kind
17 of the slings that were currently on the
18 market.

19 What were some of your suggested
20 improvements?

21 A. Well, the ones that are already
22 out there are ideas that I am holding
23 confidential. They haven't been put out
24 there yet.

1 They adopted some things that
2 were already there with other slings which
3 was the narrow trocar and a colored
4 sheathe that could be identified. So
5 those aren't hidden or protected ideas.
6 They're -- there are some ideas on the
7 table about how to, one, make the sling
8 passage more comfortable in the
9 postoperative setting for pain; and two,
10 to identify an inadvertent pass in the
11 bladder that you might miss.

12 Q. Anything about the mesh material
13 itself?

14 A. No.

15 Q. Are you still consulting for
16 Caldera?

17 A. Yes.

18 Q. So basically 2013 to 2014 to
19 present you've been consulting for
20 Caldera?

21 A. Yes.

22 Q. How much are you being paid by
23 Caldera? Is there some sort of a yearly

24 consulting rate or something like that?

264

1 A. It's an hourly rate. Just based
2 on à la carte services given.

3 Q. What is your hourly rate with
4 them?

5 A. Four hundred an hour.

6 Q. How many hours a year since 2013
7 or 2014 do you think you've spent working
8 with Caldera?

9 A. It varies. You know, if we're
10 in the middle of a product that they've
11 bought into, it could be 50 hours in a
12 year.

13 Last year was only seven or
14 eight hours. So it varies quite a bit.

15 Q. Are you aware of multiple years
16 working for them where you made more than
17 \$20,000?

18 A. Maybe two.

19 Q. How far do you think you've been
20 paid by Caldera sense you started working
21 for them?

22 A. Fifty. 50,000.

23 Q. You use Caldera slings.

24 Right?

265

1 A. I do.

2 Q. Is the Desara your sling of
3 choice?

4 MS. GERSTEL: Object to form.

5 A. It's the one I use most
6 commonly.

7 Q. What percentage of the time do
8 you use the Desara?

9 A. 75 percent.

10 Q. What percentage of the time do
11 you use one of the Ethicon TVT slings?

12 A. Ten percent.

13 Q. And what are the other products
14 you use? The other sling products you
15 use?

16 A. I use Boston Scientific, Caldera
17 and the Exact.

18 Q. So, you would use the BSC you
19 use, is that the Advantage Fit?

20 A. Yes.

21 Q. What are the differences between
22 the Desara and the TVT slings?

23 A. Well, the meshes are different.
24 The shape of the trocars are similar. The

266

1 pathways are similar. The Caldera is
2 reusable trocars and comes with the
3 ability to change direction, size and
4 shape of your trocars. The Caldera for
5 the obturator has inside-out and
6 outside-in. Those are the major -- those
7 are the differences I can think of.

8 Q. How are the meshes different
9 between the TVT slings and the Caldera?

10 A. Well, the present mesh I like to
11 use for Ethicon is the TVT-Exact. So it's
12 laser-cut and the Caldera is
13 mechanically-cut.

14 Q. Any other differences?

15 A. I'm sure there's a chart I've
16 seen where their pour Ross tee and pore
17 size have some other differences. So they

18 do, you know, on a -- on a chart of
19 mechanical properties they differ.

20 Q. The Desara is larger pore mesh
21 than the TVT-Exact.

22 True?

23 A. I think we had that one before,
24 and I thought we had -- I thought that was

267

1 the other way around, but I could be
2 mistaken.

3 Q. Is the Desara more resistant to
4 deformation than the TVT sling products?

5 A. I'm not aware of that being
6 studied officially or by myself. I don't
7 notice a difference clinically.

8 Q. So you're not aware of
9 literature that says it is?

10 A. I don't know if one of the
11 mechanical studies that pulled on each
12 thing described it in a certain way.

13 I do remember in that same
14 article that has the chart that says the
15 pore sizes and the weight, I think it also

16 discussed what happened to them under
17 stress and it probably shows different
18 properties. I don't remember when it
19 shows.

20 It behaves the same in the
21 patient for me.

22 Q. Are you aware that Caldera makes
23 the claim that their product, their TVT
24 product is -- that the Desara is more

268

1 resistant to deformation than the TVT
2 products?

3 A. I wasn't aware of that.

4 Q. So you don't have any idea what
5 that claim is based on?

6 A. I do not.

7 Q. Do you have any reason to
8 disagree with Caldera?

9 A. I would just ask them to show me
10 what it's based on.

11 Q. Do you disagree with them or no?

12 A. I don't have the knowledge to
13 agree or disagree.

14 Q. So, you use the Desara because
15 it's --

16 MR. DeGREEFF: Strike that.

17 Q. So the Desara is a
18 mechanical-cut mesh.

19 Is that correct?

20 A. Yes.

21 Q. The TVT-Exact is laser-cut.
22 True?

23 A. Yes.

24 Q. The TVT-Abbrevio is laser-cut?

269

1 A. Yes.

2 Q. And the TVT-0 has both laser-cut
3 and mechanical-cut options.

4 Right?

5 A. Yes.

6 Q. You said you worked for Boston
7 Scientific as a consultant.

8 Is that true?

9 A. Yes.

10 Q. When did you start working for
11 Boston Scientific as a consultant?

12 A. That was a ways back.

13 So, they sold the device that I
14 helped make was sold in 1996 or '97. So
15 1998 they asked me to come on since I had
16 helped to make the device together and we
17 started -- I started doing that study
18 about the using that device to make first
19 it was in a scientific role doing studies,
20 the two studies for the sacrospinous
21 suspension and for the mini incisional
22 Burch procedure. And as that relationship
23 grew, we started talking about, you know,
24 how they could improve their pelvic floor

270

1 products. I had gone to Ethicon as the
2 theme continues, I had gone to Ethicon
3 about making the needle smaller and they
4 didn't want to. So we made the Advantage
5 Fit together.

6 Q. Okay. And, so, that would have
7 been like 1996 that you started consulting
8 with BSC?

9 A. '96 or '97 is when they sold the

10 device. So my consulting would have
11 started in like '98. Somewhere in that
12 range.

13 Q. Okay. So you were not
14 consulting with them before they sold the
15 device?

16 A. Correct.

17 Q. So 1998 until when did you stop
18 consulting with BSC?

19 A. Four years ago.

20 Q. So 2015-ish? Is that correct?

21 A. Yeah, around that time. It's
22 all approximates.

23 Q. It sounds like were you doing
24 R&D type work for them, or was there some

271

1 other aspect of it?

2 A. I was teaching in labs trying to
3 teach people good -- the best technique,
4 or at least my best technique for placing
5 slings and doing the sacrospinous
6 suspension. So a lot of lab work
7 teaching.

8 I was working on R&D for the
9 slim sling. Wasn't that extensive. We
10 were just making the needle narrow and
11 putting the tube on it. You know, as far
12 as a change, it's a significant change in
13 a product.

14 They asked for my opinion on
15 some of the -- I was involved in the
16 development. They asked for my opinion on
17 some of the vaginal mesh products when
18 they started making those.

19 Q. So it sounds like they were
20 asking you for input on just kind of the
21 use of the device as well as some R&D
22 aspect.

23 Is that fair?

24 A. Product development and

272

1 teaching.

2 Q. And you currently use the BSC
3 Advantage.

4 Right?

5 A. To a small degree.

6 Q. And were you being paid by BSC
7 as a consult for that 17-year span, I'm
8 assuming?

9 A. Yes.

10 Q. How much do you think you were
11 paid in that 17 years by BSC?

12 A. That wasn't high volume per
13 year. I mean, ten a year, approximate.

14 Q. Ten thousand a year?

15 A. Ten thousand a year if I was
16 involved in a project. Maybe it was 20 on
17 a year where we were more involved in
18 focusing on something.

19 Q. So, over 15 years, maybe 150 to
20 200,000?

21 A. 15 years, yeah, somewhere in
22 that range.

23 Q. What are the differences between
24 the BSC Advantage sling and the TVT

273

1 products?

2 MS. GERSTEL: Objection; asked
3 and answered, I think.

4 THE WITNESS: Yeah, it was?

5 I'll answer it.

6 A. So, the Boston Sci slings are
7 all laser-cut. The central portion of the
8 sling is also heat treated potentially to
9 make it a little more robust in that area.
10 So it is stiffer for sure.

11 Other than that, the TVT-Exact
12 and the TVT have a very similar shape, a
13 very similar angle. You know, when I was
14 consulting with Boston Sci, we were
15 basically making a TVT that was skinnier.
16 So the shape was similar. The arc of the
17 needle is similar. You know, the porosity
18 of the mesh is slightly different. I
19 can't tell you what it is, but it's all
20 within the type one mesh characteristics.

21 Those are the major differences.

22 Q. You said you did some consulting
23 for AMS.

24 Is that right?

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1 A. Very little.

2 Q. When did you start that?

3 A. It was in the vaginal mesh era.

4 They asked me to come up and do one or two

5 labs to see what I thought of their

6 vaginal mesh. It was a one or two-gig

7 thing.

8 Q. What did they pay you for doing

9 those labs?

10 A. I think 3500.

11 Q. Total or each?

12 A. Each one.

13 That includes a trip to

14 Minnesota in the winter. So you could say

15 I paid them.

16 Q. So roughly seven grand total

17 with them?

18 A. Yeah.

19 Q. Have you done anything with them

20 since then?

21 A. No.

22 Q. How many -- since you've been

23 acting as an expert witness for Ethicon, I

24 believe you said you've given your general

1 opinion and then there's been four or five
2 case-specifics.

3 True?

4 A. Yes.

5 Q. Have you ever told Ethicon no
6 when they came to you and asked you to
7 give an opinion on a specific -- in favor
8 of a specific case?

9 A. Of a case?

10 I think we had one where, you
11 know, the materials were sent and then
12 they said look at the other ones first
13 because we're working on this. I glanced
14 at the case and looked at some of the key
15 things and I said this one may be a tough
16 one and they ended up closing that case
17 before I ever lent the opinion.

18 So, there are discussions
19 sometimes where I tell them that, you
20 know, this case looks a little difficult.

21 MS. GERSTEL: I'll just state
22 not to reveal any discussions with
23 counsel.

24 THE WITNESS: Right.

1 BY MR. DeGREEFF:

2 Q. So they settled that case before
3 you had to say no basically?

4 A. I didn't say that I said no. I
5 was evaluating it, but they settled the
6 case before I got deeper.

7 Q. So the answer is no, you've
8 never told them no on any case they've
9 asked you to be an expert witness on?

10 A. At this point, no.

11 Q. In all the case-specific reports
12 you've done for Ethicon, you've ultimately
13 enclosed that the product, i.e. the mesh
14 manufactured by Ethicon, was not the cause
15 of the plaintiff's complications.

16 True?

17 MS. GERSTEL: Object to form.

18 A. Yes.

19 Q. Have you ever given the opinion
20 that one of Ethicon's mesh products caused
21 a woman's pain or other complications?

22 A. Well, the product used by a

23 surgeon and the use of the product not
24 being used correctly is different than the

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1 product itself causing the damage. So I
2 never have thought that the product itself
3 caused the damage.

4 Q. But you've blamed the doctor in
5 some of them, in some of your --

6 A. I didn't blame the doctor. I
7 assessed the materials and assessed that
8 the technique issues were problematic.

9 Q. So you blamed the doctor
10 ultimately and said that it was the
11 doctor's fault?

12 MS. GERSTEL: Object to form.

13 BY MR. DeGREEFF:

14 Q. True?

15 A. Sometimes it was a technique
16 problem. Sometimes it was a concomitant
17 procedure and it may not be the doctor's
18 fault. If you do a posterior repair, you
19 can have dyspareunia and it doesn't mean
20 the doctor was faulty. It's a known

21 complication of other gynecologic
22 procedures that happen concurrently with
23 the mesh procedure. So it's not
24 necessarily that I'm blaming the doctor.

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1 Q. Have you ever given the opinion
2 that any mesh product caused a woman's
3 injury?

4 A. I've never given the opinion
5 that a mesh product separate from the
6 procedure caused an injury.

7 Q. You've given the opinion that
8 the opinion was somehow done wrong and
9 that was the cause?

10 MS. GERSTEL: Object to form.

11 A. If there's a problem with a
12 procedure when you're using mesh it can
13 lead to complications. It wouldn't happen
14 if the procedure was done right. The mesh
15 characteristics I don't think would have
16 harmed the woman.

17 Q. Do you have any understanding
18 why you were chosen as an expert witness

19 for Ethicon in this litigation?

20 A. I've got a good reputation in
21 the field for 23 years. I do good
22 clinical work. I publish. I'm easy to
23 get along with.

24 Q. And you have a been an Ethicon

279

1 consultant or expert witness for 17 years
2 now.

3 Is that right?

4 A. Well, the expert witness now is
5 for about three, three-and-a-half years.
6 And the Ethicon consulting was from, I
7 would have to look back at the transcript.
8 It was probably five to ten years.
9 They're not continuous, but --

10 Q. Well, you started in 2002
11 consultant for them.

12 Right?

13 A. Approximately that.

14 Q. You consulted with them until
15 roughly 2012.

16 Right?

17 A. Well, I think there was -- in
18 2012, I think that might have been the --
19 there was a big gap. So yes, from a time
20 frame, you go to 2012. But I think if
21 you've got the records from when I worked
22 for them, there was a pretty big gap. I
23 was not doing a lot of Gynecare work for a
24 few years and then they asked me and asked

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1 me if I would come take a look -- I think
2 there's one data point that's make that go
3 look extend. So it may be five to eight
4 years and not twelve years just because I
5 think that 2012 is an outlier. But you'd
6 have to look at -- I know you have the
7 records of everything that I've done. So
8 we'd have to look more closely at it.

9 Q. So we're looking at eight to
10 eleven years where you were either a
11 consultant or an expert for Ethicon in the
12 last 17.

13 Right?

14 A. Sounds about right.

15 Q. And you've been using their
16 product since 2000?

17 A. Yes.

18 MR. DeGREEFF: We can take a
19 break.

20 (Recess taken.)

21 BY MR. DeGREEFF:

22 Q. Sir, do you remember doing any
23 work for Astellas?

24 A. Yes.

281

1 Q. And what was that?

2 A. A pharmaceutical company made a
3 drug for the overactive bladder.

4 Q. Do you do some consulting for
5 them, it looks like?

6 A. Yes.

7 Q. And when did you do that?

8 A. I don't know the exact years.
9 It would probably be like three years ago
10 to six years ago, so.

11 Q. 2013 to 2016?

12 A. Yeah.

13 Q. Do you have any idea how much
14 you were paid by them?

15 A. Maybe 5,000 a year.

16 Q. So maybe 15 total?

17 A. Yeah.

18 Q. I want to discuss, you told me
19 earlier you were paid about 50,000 by
20 Caldera.

21 Do you remember that?

22 A. Yes.

23 Q. I want to talk to you about
24 that.

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1 Do you remember being paid \$6500
2 by Caldera in 2013?

3 A. I wouldn't be able to recall the
4 yearly in this meeting.

5 Q. Do you know what the open
6 payments data is on the CMS website?

7 A. I assume it's a public record of
8 what I've been paid for various
9 activities.

10 Q. Right.

11 If Caldera reported that they
12 paid you \$6,500 in 2013, would you
13 disagree with that?

14 A. I would have to check my
15 records. I don't know that those records
16 are -- I do know that some of the online
17 records of what I've been allegedly paid
18 were wrong.

19 So, I would say that we are
20 discussing consulting years ago, ranges
21 and payments, and I would suggest that I
22 come up with the actual payments from
23 payroll would be something I'd like to do.

24 Q. So you want to go chase down for

283

1 me all of your accounting records for
2 everything you've received from all of
3 these pharmaceutical companies?

4 MS. GERSTEL: Object to form.

5 A. Well, I don't know we're -- you
6 know, we're guessing at a lot of
7 activities with a lot of companies across
8 20 years. It seems like the -- I don't

9 know how often target they would be.

10 I do know the online stuff, I
11 looked one time it was off by a digit and
12 we do have to contact them much there was
13 one time I had to contact them to make it
14 corrected.

15 Q. Well, in 2014, do you remember
16 being paid \$25,000 by Caldera?

17 A. I don't remember the yearly
18 number.

19 Q. Does that sound inaccurate to
20 you?

21 A. There was a year or two where I
22 was doing a lot of work.

23 Q. In 2015 do you remember being
24 paid \$25,000 again by Caldera?

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1 A. I don't remember the number, but
2 it's plausible. As I said, there were a
3 couple of years where it was heavy.

4 Q. In 2016, do you recall being
5 paid \$18,600 by Caldera?

6 A. It's certainly possible.

7 Q. In 2017, do you recall being
8 paid \$8,000 by Caldera?

9 A. That sounds familiar.

10 Q. So I get more like \$80,000 paid
11 to you by Caldera.

12 Does that sound accurate to you?

13 A. It sounds like the records you
14 have show that.

15 Q. Do you disagree with that? Does
16 that sound out of line?

17 A. It may be right. It may be plus
18 or minus 20.

19 I will go to their accounting
20 and ask them.

21 It doesn't sound erroneous.

22 MR. DeGREEFF: Sir, I'm going to
23 hand you what I'm going to mark as
24 Deposition Exhibit 10.

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1 (Lind Exhibit 10, Consulting
2 Agreement dated as of January 3, 2002
3 between Lawrence Lind, M.D. and
4 Ethicon, Inc., Bates No.

5 ETH.MESH.16009738 to 16009743, was
6 marked for identification, as of this
7 date.)

8 BY MR. DeGREEFF:

9 Q. Sir, does this appear to be a
10 consulting agreement between you and
11 Ethicon?

12 A. Looks like it.

13 Q. What is the date of that?

14 A. 2002.

15 Q. January 3rd of 2002?

16 A. Yep.

17 Q. Does that sound familiar as
18 about the time you started working for
19 Ethicon as a consultant?

20 A. It's about where I thought it
21 was.

22 And it looks clearly it's a
23 document that's real.

24 Q. If you look at under Section 1

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1 Consultant, my only question is with that
2 paragraph is there's a spot in it that

3 says: Keep records of hours worked and
4 cost of materials used.

5 Was that something that you
6 would have done?

7 A. You know, the consulting for
8 them was not at home working on documents.
9 They would call me to do a lab. It was a
10 half-day lab. They'd pay \$3,000 and it
11 was a one at a time thing.

12 So, there really wasn't any
13 recordkeeping much you'd go. You'd submit
14 one at a time. It wasn't a kind of like a
15 cumulative work that was being added that
16 you recorded. So I would say I kept
17 records, but it was one at a time and once
18 you did it, I didn't keep track after
19 that.

20 Q. So I guess my question is are
21 there any records in existence that would
22 have a detail of the hours worked under
23 this consulting agreement?

24 A. I don't have it and I don't know

1 if Ethicon would have it.

2 Q. Would that have been something
3 you would have submitted to Ethicon?

4 A. As I said, it was a one day at a
5 time type of working agreement. So even
6 though it's instructing to keep hours, I
7 think that's requesting to kind of keep
8 the accounting in order. The way I
9 worked, it was just a, you know, once
10 every few weeks or few months, they asked
11 me to come to do something and I went and
12 I submitted for that one day.

13 So, there were not -- there
14 aren't records, I don't have a spreadsheet
15 or a record of the hours worked.

16 Q. Okay.

17 I don't see that I ever asked
18 you that, but how much do you think you
19 were paid by Ethicon as a consultant? Not
20 as a expert witness, but as a consultant?

21 A. I don't know. It started a long
22 time ago. Spanned a long period. There
23 were periods with big gaps where I didn't
24 do much at all, and there were periods

1 where I did a lot.

2 So I really cannot conjure a
3 guess. I don't know if it's 20,000 or a
4 hundred thousand. I really don't know.

5 Q. And who would know that answer,
6 if not you?

7 A. I don't know if Ethicon has the
8 records or if their accounting goes back
9 that far.

10 Q. So, if you look at page 3 of
11 this agreement, the term of the agreement
12 commenced on January 3rd of 2002 and seems
13 to have terminated on February 28th of
14 2002.

15 Do you have any idea why it was
16 so short?

17 A. You know, I'd have to read the
18 whole agreement.

19 As I recall, there was a time
20 where anyone -- the contracts they had had
21 things that said you couldn't work with
22 anyone else. So, I said well, you know, I
23 have ideas I'm working on and you're

24 rejecting them. So, I don't know if

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1 that's why.

2 So this may have been made
3 because I didn't agree to some of the
4 terms of their long-term agreement, but
5 they wanted me to come for this one
6 session, so we made a short-term contract.
7 So it does seem odd.

8 Q. I think the situation you're
9 talking about was in 2010.

10 And maybe if you turn to page 4
11 of Exhibit 10, that will kind of clarify
12 it for you. If you look at 6 and 7,
13 paragraph 6 and 7.

14 A. Yeah, it looks like it's an
15 invitation to go to one session, abdominal
16 guides training session.

17 Q. That's what I was going to ask.

18 So, it looks like they were
19 paying you \$3,000 for coming to a
20 abdominal guides training session?

21 A. Right.

22 Q. Did you get that \$3,000 just to
23 show up, or did you have to teach?

24 A. I was definitely teaching

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1 abdominal guides. They weren't -- I would
2 be one of the people teaching it, not
3 learning how to do it.

4 Q. How long was that training
5 session?

6 A. They usually were a half-day to
7 six hours. Four to six hours.

8 Q. Where did those take place?

9 A. They were in a number of
10 locations. It was various places that had
11 access to cadavers. So I don't know where
12 it took place, but the closest it would be
13 in 2000 -- it wasn't on Long Island until
14 later in our agreements because we didn't
15 have cadaver labs. So it would either be
16 Manhattan, New Jersey.

17 Q. Somewhere in the New York
18 metropolitan area?

19 A. Yeah. I wasn't flying for this.

20 Q. And they were essentially paying
21 you \$3,000 for a half-day participation?

22 A. Well, as I said, it would be
23 four to six hours, plus the transportation
24 and time. So, you know, door to door, it

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1 would certainly be more than eight hours.

2 Q. Did they pay you for your
3 transportation and hourly rate also?

4 A. They paid the amount and then
5 just incurred costs for transition. It
6 wasn't an hourly rate on top of that.

7 Q. So \$3,000 for roughly eight
8 hours.

9 Is that right?

10 A. Yeah.

11 MR. DeGREEFF: I'm going to hand
12 you what I've marked as Deposition
13 Exhibit 11.

14 (Lind Exhibit 11, Clinical Study
15 Agreement between Gynecare and North
16 Shore University Hospital, Bates No.
17 ETH.MESH.00412092 to 00412098, was

18 marked for identification, as of this
19 date.)

20 BY MR. DeGREEFF:

21 Q. Can you tell me what that is?

22 A. Clinical study agreement.

23 Q. And the term of that agreement

24 is April 4th, 2002 through the end of

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1 June, through June 30th of 2004.

2 Correct?

3 A. Right.

4 Q. This was between Gynecare, which
5 is a division of Ethicon, correct?

6 A. Yes.

7 Q. And your institution with you
8 and Dr. Garely designated as the looks
9 like the primary people in charge of this?

10 A. Investigators.

11 Q. Is that correct?

12 Who is Dr. Alan Garely? Do you
13 know him?

14 A. He was a previous partner in my
15 practice, and he now practices in

16 Manhattan and south shore of Long Island.

17 Q. Do you know him personally?

18 A. You know, I mean, we were
19 partners for three years. So I did know
20 him personally. We don't socialize at
21 present.

22 Q. Is he a good doctor?

23 A. He's a good surgeon. I don't
24 think -- again, I haven't seen him take

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1 care of patients in 15 years.

2 Q. I mean, do you have any
3 criticisms of him as a physician?

4 MS. GERSTEL: Object to form.

5 A. He could get upset with someone
6 and then it wasn't a good scene.

7 Q. Okay. That's not really him as
8 a surgeon. It sounds like maybe you --

9 A. I haven't seen him in a
10 practicing situation for 15 years. So I
11 really don't think I can say anything.

12 Q. Okay.

13 So, Dr. Garely was one of the

14 investigators hired by Ethicon to do this
15 clinical study agreement with you --

16 A. Yes.

17 Q. I mean to do this clinical study
18 with you.

19 Do you know when was the last
20 time you spoke to Dr. Garely?

21 A. A couple months ago.

22 Q. Do you know whether he currently
23 uses the TVT-0, TVT or TVT-Abbrevio?

24 A. I don't.

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1 Q. Have you ever been provided with
2 any of the testimony or documentation of
3 what he told Ethicon about those devices?

4 A. I think I saw one of his mesh
5 reports. I don't think I saw a sling
6 report.

7 Q. So, as you sit here, do you have
8 any idea what he told Ethicon about the
9 TVT-0, TVT-E and TVT-Abbrevio?

10 A. I don't.

11 Q. Is it your understanding that

12 Dr. Garely is now a plaintiff's expert in
13 the transvaginal mesh litigation?

14 A. I do understand that.

15 Q. And you reviewed his report?

16 A. I reviewed his mesh report.

17 Q. When you say "his mesh report,"
18 are you talking about with regard to the
19 Prolift?

20 A. Yes.

21 Q. So, this is a former consultant,
22 or I guess someone who is a former
23 investigator on a study done by Ethicon
24 who's now providing testimony for the

295

1 women injured by Ethicon devices.

2 Is that right?

3 MS. GERSTEL: Object to form.

4 A. Looks like he was a previous
5 participant in this study and he is now a
6 plaintiff's expert, as you described.

7 Q. Well, plaintiff meaning the
8 women who are claiming injuries.

9 True?

10 A. Yes.

11 Q. If you look at paragraph 1 where
12 it says: Performance of study.

13 As the principal investigator,
14 you were to perform the study in
15 accordance with the protocol.

16 Right?

17 A. Right.

18 Q. Who determined the protocol?

19 A. I would have to look at the
20 protocol to comment on that. But I would
21 say that any study I enrolled in, I would
22 have to believe that it was a protocol
23 that I agreed with. So there can be
24 suggestions from a company as to what they

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1 might want to happen, but I would never
2 have a -- subject my patients to any
3 protocol that I didn't specifically take
4 responsible for if I was a principal
5 investigator.

6 Q. Well, Ethicon determined the
7 protocol that was used.

8 Right?

9 A. I am ultimately responsible for
10 the protocol that gets submitted to the
11 IRB.

12 Q. I understand.

13 A. How much of the protocol was
14 created by them and edited by me or
15 created totally by me I don't think we can
16 answer at this meeting.

17 Q. At you look at paragraph 3
18 Financial Consideration and Payment
19 Schedule.

20 You see where I'm at?

21 A. Mm-hm.

22 Q. It says: The total price for
23 the conduct and the completion of study as
24 well as the payment schedule is outlined

297

1 in Schedule B.

2 Did I read that correctly?

3 A. Yep.

4 Q. Look at Schedule B, if you
5 would. It's on page 6.

6 Are you there?

7 A. Yes.

8 Q. It appears that the total
9 payment being made by Ethicon is \$11,000.

10 Is that correct?

11 A. That's the planned -- that's the
12 budget for the -- for the study. Right.

13 How much was actually paid with
14 how many subjects, we don't know. This is
15 the schedule of payments ahead of time of
16 what would be paid. Each line item would
17 have to be carried out to be paid that.
18 It's not paid in advance, so.

19 Q. Okay. That's the project the
20 \$11,000 for the payment for the study?

21 A. Right.

22 Q. And this was between 2002 and
23 2004 that you were conducting this study?

24 A. Yes.

298

1 Q. So, the title of the study is "A
2 clinical assessment of patients undergoing
3 Gynecare TVT with abdominal guides for the

4 treatment of stress urinary incontinence."

5 Correct?

6 A. Right.

7 Q. And what was the ultimate goal
8 of the study?

9 A. You know, they had a retropubic
10 sling, the standard TVT that went from
11 bottom up, from the vagina upward, and
12 there were a -- from the urology teaches
13 of slings of long ago there's a different
14 way of passing a sling that started from
15 the top down, which a lot of urologists
16 favor. So the -- it was a design of
17 appear instrument by Gynecare to try to
18 add that to their product line and to give
19 those who felt that that was a safer
20 passage the opportunity to go from the top
21 down. So the purpose of this study was to
22 look at efficacy of safety of a sling that
23 went from the top down rather than the
24 bottom up.

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1 Q. And what was the result?

2 A. I don't think it got off the
3 ground and got enough numbers for
4 enrollment, because I don't think I ever
5 saw a publication from it.

6 MR. DeGREEFF: Sir, I'm going to
7 hand you what's been marked as
8 deposition Exhibit 12.

9 (Lind Exhibit 12, Secrecy
10 Agreement dated January 19, 2004
11 between Gynecare and Lawrence Lind,
12 MD, Bates No. ETH.MESH.09464276 to
13 09464279, was marked for
14 identification, as of this date.)

15 BY MR. DeGREEFF:

16 Q. Can you tell me what that is?

17 A. It's a privacy agreement to
18 discuss intellectual property.

19 Q. It's actually better than that.
20 It's called a Secrecy Agreement.

21 Right?

22 A. That's how they titled it.

23 Q. And that's between you and
24 Gynecare.

1 Correct?

2 A. Right.

3 Q. And Gynecare is a part of
4 Ethicon?

5 A. Yes.

6 Q. I want to ask you a couple of
7 questions.

8 First is in paragraph 1 on the
9 front page.

10 You see where I'm at?

11 A. Yep.

12 Q. It states that it's to determine
13 whether to enter into a mutually
14 attractive business arrangement.

15 Did I read that correctly?

16 A. I see it.

17 Q. What does that mean? What was
18 the mutually attractive business
19 arrangement that you were trying to decide
20 whether to enter into with Ethicon?

21 MS. GERSTEL: Object to form.

22 A. This is 2004. So this may have
23 been when I wanted to propose to them the
24 slim modification of the TVT. So I was

1 disclosing some personal information that
2 I didn't have intellectual property on,
3 but I had drawings. I had writings. I
4 had sealed documentation that I had come
5 up with this idea.

6 So, I don't know for sure, but I
7 think that this is a scenario to sit down
8 and talk about an idea that I had and, you
9 know, usually in this situation, if a
10 company likes your idea, then they
11 purchase it from you and there's a
12 business arrangement made. I've never had
13 one of those arrangements, but I'm
14 extrapolating. I can't say for certain
15 that's what we were doing here. But this
16 sounds like a scenario where I'm
17 presenting them with an idea and they're
18 going to decide whether there's something
19 mutually agreeable that would come out of
20 this.

21 MS. GERSTEL: I'm just going to
22 place a late objection that that -- I

23 believe that that's a
24 mischaracterization of the document

302

1 and the agreement.

2 BY MR. DeGREEFF:

3 Q. So, would you have been asking
4 them to partner up on your idea? Is that
5 kind of what you were doing?

6 MS. GERSTEL: Object to the
7 form.

8 A. Well, when you have an idea, you
9 want to present it. And I'm not in a
10 position to take a idea and make it into a
11 sling. So you go to a reputable company
12 that's right now the leader in sling
13 products and you bring your idea to them
14 to see whether they like it.

15 So, partner up, you could call
16 it partner up or you could call it a
17 routine scenario where someone with an
18 idea brings an idea to a company and if
19 it's deemed valuable, there's a business
20 arrangement made to purchase the

21 intellectual property and there's a
22 financial arrangement made with them.

23 Q. Well, if they're the leader
24 currently, then why didn't you go to them

303

1 with your current device? Why did you go
2 to BSC and Caldera instead?

3 A. Because my relationships with
4 them are more current.

5 Q. It states: The parties further
6 agree not to disclose the relationship
7 between the parties or the existence of
8 this agreement to any third party without
9 the consent of the other.

10 And there's a three-year
11 effective date on that.

12 Did I read that correctly?

13 A. Yeah.

14 Q. So, you weren't even, under this
15 secrecy agreement, you weren't even
16 allowed to disclose that you had a
17 relationship with Ethicon.

18 Is that what this says?

19 A. It says that I would have to
20 tell them if I was telling someone else.

21 Q. So, when you were offering your
22 patients the TVT sling devices, did you
23 disclose to them that you had a consulting
24 relationship with Ethicon and several

304

1 other sling manufacturers?

2 A. I did and I do.

3 Q. Did this prohibit you from doing
4 that?

5 MS. GERSTEL: Object to the
6 form.

7 A. No.

8 Q. Why do you disclose your
9 consulting relationship with Ethicon and
10 other sling manufacturers to your
11 patients?

12 A. Because you want to make sure I
13 have a discussion that lets them know I
14 work towards betterment and improvement of
15 these products all the time. That means I
16 work with the companies. And there are

17 payments made sometimes for that
18 consulting work, and I don't want them to
19 discover that and feel that I hid
20 something that they would think was, you
21 know, financial motivation. I tell them
22 the relationship. I tell them why I use
23 the product, and I tell them why I'm
24 working with them.

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1 Q. Okay.

2 A. Seems like the responsible thing
3 to do.

4 Q. Right.

5 Because being paid by somebody
6 can create a bias towards using a product.
7 Right?

8 A. Correct.

9 MR. DeGREEFF: I'm going to mark
10 for you deposition Exhibit 13.

11 (Lind Exhibit 13, e-mail chain
12 ending June 15, 2004, Bates No.
13 ETH.MESH.11003781 to 11003783, was
14 marked for identification, as of this

15 date.)

16 BY MR. DeGREEFF:

17 Q. So, I have handed you what
18 appears to be an exchange, an e-mail
19 exchange from it's the June of 2004 date
20 range.

21 Does that look accurate?

22 A. This is 2004 communications,
23 right.

24 Q. And if you look at the initial

306

1 two e-mails on the chain, meaning the
2 earliest in time, you are a recipient on I
3 guess two of the three earliest you're a
4 recipient on those e-mails.

5 Correct?

6 A. Please find the attached signed
7 contract for your Gynemesh procedure
8 videos. The original and copies have been
9 sent to Jeff Kraut by the courier.

10 I see that.

11 Q. And if you look the to line,
12 this e-mail was sent to you.

13 Correct?

14 A. Which line?

15 Yes.

16 Q. And who is Giselle Bonet?

17 A. I don't recall.

18 Q. And the subject line of this

19 exchange is called "Procedure Videos

20 Signed Contract."

21 Did I read that correctly?

22 A. Yep.

23 Q. I mean, did you do some form of

24 a video for Ethicon?

307

1 A. I don't think I did a beginning

2 to end video. I think perhaps maybe in a

3 lab they were filming some steps of

4 anatomic passage of something.

5 I -- I don't -- I cannot recall

6 a video that's got my name on it or in the

7 credits that the video maker of one of

8 these sling videos.

9 I think that sometimes when you

10 go to their labs and you work on stuff,

11 they ask you to sign permissions, or if,
12 you know, maneuvers you've done or -- or
13 anatomy you've shown might be used for
14 videos, and this might be like a little
15 segment video permission. But I do not
16 recall a video with my name on it that I
17 made for -- you know, beginning to end for
18 Ethicon.

19 Q. Well, if you look a little
20 further up in the chain on the same page,
21 there's an e-mail to you that says:
22 Larry.

23 That's you, right?

24 A. Yeah.

308

1 Q. Would like to process this
2 payment in June. Need paperwork back
3 before 6/21.

4 Did I read that correctly?

5 A. Yep.

6 Q. So, were you paid to do this
7 video?

8 A. I don't know what I was doing

9 there. There's some -- I don't know -- I
10 don't know what this -- I don't know what
11 this is.

12 Q. Okay.

13 A. I really don't know what it is.

14 Q. If you look on the next page,
15 there's an e-mail -- I mean on the front
16 page, I guess. There's an e-mail to you
17 on June 11th from Marianne Kaminski with
18 Ethicon stating: We have the signed
19 contract. We will process the payments.

20 Did I read that correctly?

21 A. Okay.

22 Q. So, appears you were paid for
23 doing a Gynecare -- excuse me. A Gynemesh
24 procedure video.

309

1 Right?

2 A. There's something I was doing
3 that was either used as part of a video or
4 participated in making a video. But as I
5 said, I don't recall.

6 As I've described it, it could

7 just be segments of something I did in lab
8 that was filmed.

9 I don't believe that I made them
10 a video from beginning to end. But I was
11 clearly, by this set of e-mails, paid for
12 work I did that was used as or as part of
13 creating a video.

14 Q. I really ask because I'm
15 wondering if I'm in the presence of a
16 movie star. That's really where I was
17 going with that. And if I could get an
18 autograph maybe later.

19 A. Well.

20 Q. All right.

21 A. But I do look like a couple of
22 them.

23 MR. DeGREEFF: Sir, I'll
24 happened you what I'll marked as

310

1 deposition Exhibit 14.

2 (Lind Exhibit 14, Q CDA Log,
3 Bates No. ETH.MESH.15359953 to
4 15359976, was marked for

5 identification, as of this date.)

6 BY MR. DeGREEFF:

7 Q. This is titled Q CDA log.

8 Have you ever seen this before?

9 A. May have.

10 Q. If you look on page 11, the
11 Bates number at the bottom of it has a
12 last three of '963.

13 A. Are they numbered?

14 Q. Down here (indicating). The
15 Bates number ends in '963. That's called
16 a Bates number.

17 A. Okay.

18 Q. If you look at the second column
19 over, it says: With whom.

20 A. Got it.

21 Q. And then one, two, three, fourth
22 one down says: Dr. Larry Lind.

23 I'm assuming that's you?

24 A. Yes.

311

1 Q. And that shows that there's a
2 topic next to it that says: Evaluating

3 information for discussions regarding
4 device evaluations.

5 Do you know what that means?

6 A. Sounds like I'm looking at their
7 devices and discussing it.

8 Q. If you look at the column next
9 to that, it says type and SA is written.

10 Do you know what that means?

11 A. Nope.

12 Q. Does it mean secrecy agreement?

13 MS. GERSTEL: Objection.

14 A. I don't know.

15 Q. Then there's a column further
16 over that has a term that says: Term and
17 it says 3.

18 Do you see that?

19 A. Yep.

20 Q. And it shows date and years
21 columns that says 12/19/define to
22 12/20/2012.

23 Do you see that?

24 A. Yep.

1 Q. So, were you under some form of
2 an agreement with them from 12/19 of 2009
3 to 12/20 of 2012?

4 A. Looks like they have a contract.
5 I don't know if this CDA log is accurate.
6 I'd like to see that contract.

7 I can certainly tell you between
8 those years, I do not have a lot of
9 activity with them. That's for sure.

10 Q. If you look at the originator
11 column, who is V. Zaddem?

12 A. I don't know what her position
13 is now. I recall her name.

14 Q. Is it an Ethicon employee?

15 A. I assume it was someone
16 organizing or handling the contract, but I
17 don't know who it is.

18 Q. Do you know who Pete DeCosta is?

19 A. I do not.

20 Q. During this three years --

21 MR. DeGREEFF: Strike that.

22 Q. Do you have any idea how much
23 you were being paid under this three years
24 of contracts?

1 A. I think there were very few
2 events. I was usually paid in the same
3 amount by them.

4 Q. The person below you on this
5 list is Dr. Elizabeth Kavalier.

6 Do you know her?

7 A. Yes.

8 Q. How do you know her?

9 A. She was a urologist in
10 Manhattan. So we -- I get some of her
11 patients, she gets some of mine, and when
12 we do this pelvic floor society meeting in
13 the city, she sometimes attends. I think
14 she was -- I think she was at the Prosima
15 lab that I did with them in this time
16 period, and I think that was probably the
17 only thing that I did with them in this
18 time period. I'm guessing, but I remember
19 I wasn't doing a lot and they really
20 wanted me to look at this Prosima.

21 Q. Are you aware that she's also a
22 witness for Ethicon in the transvaginal
23 mesh litigations?

24 A. Yes.

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1 Q. And you're aware that she was
2 also a consultant for Ethicon prior to
3 becoming an expert witness?

4 A. Yes.

5 Q. Are you aware of any expert
6 witness for Ethicon in this litigation
7 that was not a paid consultant first?

8 MS. GERSTEL: Objection.

9 A. I don't have an answer to that.

10 Q. Then if you look a couple pages
11 later where it says '965 as the last three
12 of the Bates number.

13 A. Okay.

14 Q. There's another in the column
15 that says with whom, if you go four down,
16 it says Lawrence Lind.

17 I'm assuming that's also you?

18 A. I see it.

19 Q. And a the column that says topic
20 says: Provide consulting services to
21 Ethicon on behalf of Ethicon.

22 Did I read that correctly?

23 A. I see it.

24 Q. It looks like you were under a

315

1 master consulting agreement from 8/31 of
2 2010 to 12/31 of 2011.

3 A. I see it.

4 Q. Does it sound accurate?

5 A. Yes.

6 Q. What did you do for Ethicon as
7 part of the consulting services from 2010
8 to 2011?

9 A. I don't recall.

10 Q. So, this was a second agreement
11 with Ethicon that was covering the years
12 2010 to 2011.

13 Right?

14 We just looked at another one.

15 A. Those are the dates.

16 Q. Do, during that time period, you
17 had multiple agreements with Ethicon?

18 A. It looks like I had these two.

19 MR. DeGREEFF: Sir, I'm handing

20 you what I've marked as deposition

21 Exhibit 15.

22 (Lind Exhibit 15, e-mail chain

23 ending October 1, 2010, Bates No.

24 ETH.MESH.03642725 to 03642726, was

316

1 marked for identification, as of this

2 date.)

3 BY MR. DeGREEFF:

4 Q. Sir, I acknowledge that you are

5 not on this document. And really what I

6 want to ask you is there's a discussion

7 here about you, about your contract in

8 which some employees of Ethicon state

9 they're going to look to terminate the

10 marketing contract with you.

11 Do you see where I'm at on that?

12 A. Looking to terminate it.

13 Q. Yes.

14 A. Okay.

15 Q. Do you see where I'm at?

16 A. Yep.

17 Q. And it looks like the reason,

18 based on the e-mail above that, the reason
19 that they wanted to terminate the
20 marketing contract is because you had
21 signed an R&D agreement under which you
22 were going to get a different rate.

23 Right?

24 A. I wasn't aware as of this date

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1 that I had a marketing agreement. My
2 understanding was always as consulting
3 services for education and research and
4 development. So I would need to see the
5 marketing agreement. I haven't seen
6 anything that we've looked at today that
7 says marketing.

8 I do here that they seem to feel
9 that I had one and that they want to
10 change it.

11 Q. Why do you think they considered
12 you to have a marking contract?

13 What kind of marketing were you
14 doing for them?

15 MS. GERSTEL: Objection.

16 A. I wasn't.

17 Q. Were you giving lectures for
18 them?

19 A. In labs I would teach the
20 surgery and give educational lectures. I
21 consider that education. If you consider
22 it marketing at the same time, that's a --
23 I don't know if that's a legal term or a
24 judgment call of what you're doing, but I

318

1 was educating.

2 Q. In 2010, you were, based on this
3 e-mail, you were also consulting for
4 Boston Scientific.

5 Right?

6 A. Yes.

7 Q. And you were wanting to craft
8 the language of your consulting --

9 MR. DeGREEFF: Strike that.

10 Q. You were wanting to craft the
11 language of your R&D agreement with
12 Ethicon to avoid any conflict to what you
13 were doing for Boston Scientific.

14 Is that something you remember?

15 MS. GERSTEL: Objection.

16 A. Yes. The contract said I
17 couldn't work with anyone else on slings
18 or incontinence materials, but I was
19 already doing that with Boston Scientific.
20 So I asked them to restrict the scope to
21 repair a prolapse.

22 Q. And if you look on the earliest
23 e-mail on this exhibit, it says: There's
24 a master consulting agreement for Dr.

319

1 Lind. And it says: The contract term is
2 one year beginning 2/25/10 and ending
3 2/25/11.

4 Did I read that correctly?

5 A. Yep.

6 Q. So that would be a third
7 contract during that same time period.

8 Right?

9 A. That's what the e-mail says.
10 I haven't seen any contracts.

11 MR. DeGREEFF: Sir, I'm going to

12 hand you what I've marked as
13 deposition Exhibit 16.

14 (Lind Exhibit 16, e-mail chain
15 ending April 28, 2010, Bates No.
16 ETH.MESH.02033638 to 02033639, was
17 marked for identification, as of this
18 date.)

19 BY MR. DeGREEFF:

20 Q. This again is this is an e-mail
21 about an edit you were requesting to a
22 contract in April of 2010.

23 Right?

24 A. Yep.

320

1 Q. If you look at this first
2 e-mail, the longer one, it says: I found
3 Dr. Lind has existing contacts with ProfEd
4 and marking activities for product
5 evaluation, written materials, market
6 reviews, advisory boards and company
7 sponsored speaker programs at a rate of 15
8 hundred dollars a day.

9 Did I read that correctly?

10 A. Mm-hm.

11 Q. Company sponsored speaking
12 programs, were you speaking on behalf of
13 the company, of Ethicon?

14 A. Only at labs.

15 Q. At labs?

16 A. Yes.

17 Q. And again, they're considering
18 you to have a contract for marketing
19 activities.

20 Right?

21 A. It does indicate that. I do not
22 recall ever working on marketing.

23 Q. Certainly it appears that
24 Ethicon believed that they had a marketing

321

1 contract with you.

2 Right?

3 MS. GERSTEL: Objection.

4 A. I think what happened is we got
5 involved in a time frame where companies
6 and hospitals appeared doctors started
7 recognizing compliance, and so that

8 wording had to be very specific. So, they
9 might have had stuff in the previous
10 agreements that had to do with marketing,
11 et cetera, et cetera, which is consulting
12 that I do not do. I only do work with the
13 R&D people. In fact, I don't interact
14 with the marketing people. It's part of
15 the rules.

16 So this is, I think, something
17 to get the accounting and compliance in
18 order that my role is for R&D, which is
19 what it always was.

20 Q. Whatever the case may be, we
21 looked at multiple e-mails now where
22 Ethicon refers to one of their contracts
23 with you as a marketing contract.

24 Right?

322

1 MS. GERSTEL: Objection.

2 A. I think those referrals to my
3 contracts and my role in there are wrongly
4 described.

5 Q. Regardless, that is the

6 terminology Ethicon is using, right?

7 A. And I am challenging it.

8 Q. Then if you look at down below
9 there's an asterisk that says: These
10 activities are unique to Dr. Lind because
11 he uses competitor devices regularly.

12 Did I read that correctly?

13 A. Yes.

14 Q. And as we discussed earlier, you
15 use primarily the Caldera device
16 currently.

17 Right?

18 A. Currently.

19 At the time of this contract, I
20 think they were more interested in the
21 cadaver lab projects I did with Boston
22 Scientific.

23 Q. Gotcha.

24 So, this says: Here is what I

323

1 recently learned from Scott Jones in
2 marketing.

3 Do you know Scott Jones?

4 A. No.

5 Q. It says: In 2009, the doctor
6 agreed to \$1500 a day for Ad Board work,
7 which was the rate all participants
8 received for that event.

9 Did I read that correctly?

10 A. Everything you're reading you're
11 reading correctly.

12 Q. So, were you being paid \$1500 a
13 day for advisory board work?

14 A. That's what it says.

15 Q. And what does that advisory
16 board work mean?

17 A. You come and look at products.
18 You may be in a lab working on
19 development, discussing the products in
20 the setting of a cadaver lab. You may be
21 sitting around a table with other experts
22 holding mesh, feeling mesh, holding
23 devices, giving feedback as to what works,
24 what doesn't work, which directions can

324

1 they go.

2 Q. And then the last sentence on
3 this page leading to the next page says:
4 Over the past weekend, doctor made a
5 comment to one of our associates that he
6 was angered that he had signed at such a
7 low rate. Especially since he is
8 compensated by our competitors at three
9 thousand dollars a day for working with
10 R&D.

11 Did I read that correctly?

12 A. Yes.

13 Q. So, you were upset that you were
14 only getting paid 15 hundred dollars a day
15 by Ethicon when your competitors were
16 paying you \$3,000 a day.

17 Right?

18 MS. GERSTEL: Objection.

19 A. I see the facts that are on this
20 sheet.

21 Q. Is that your recollection?

22 A. I don't have independent
23 recollection.

24 Q. Do you have any reason to

1 dispute this?

2 A. Not really.

3 Q. And what competitors were paying
4 you \$3,000 a day in 2009 and 2010?

5 A. Probably Boston Scientific.

6 Q. It also says: Also, this
7 surgeon has tried our pelvic floor
8 products many times, but he prefers to use
9 our competitors' products.

10 Did I read that correctly?

11 A. Yes.

12 Q. And then they go on to say:
13 What I found out is that ProfEd, I guess
14 professional he had care and caution and
15 marketing used to use Dr. Lind heavily as
16 a KOL similar to how Dr. Vincent Lucente
17 is consulted currently. However, they do
18 not anticipate his services as specified
19 in his existing contracts because he does
20 not use Ethicon's PFR kits.

21 Did I read that correctly?

22 A. Yep.

23 Q. Do you know what a KOL is?

24 A. Key opinion leader.

1 Q. Were you a key opinion leader
2 for Ethicon?

3 A. I was a consultant. If they
4 called me that, they chose to call me
5 that.

6 It wasn't a badge you earned.

7 Q. Do you disagree that you were a
8 key opinion leader for Ethicon?

9 A. I think at times they thought I
10 was and at times they thought I wasn't.
11 When I came to them with the slim sling
12 design, they told me to get lost, so.

13 Q. Okay.

14 A. My opinions weren't very
15 well-respected or received then.

16 Q. So you were a key opinion leader
17 for Ethicon when you were agreeing with
18 them.

19 Is that what you're saying?

20 MS. GERSTEL: Objection.

21 A. I don't have an answer for that.

22 Q. And it seems here that

23 professional education and marketing were
24 using you heavily.

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1 Correct?

2 A. That's what it reads.

3 Q. Who is Dr. Vincent Lucente?

4 A. He's a urogynecologist in
5 Pennsylvania.

6 Q. Was he a key opinion leader for
7 Ethicon?

8 MS. GERSTEL: Objection.

9 A. I guess he was.

10 THE WITNESS: I'm sorry. I know
11 time is getting tight. I'm going to
12 use the restroom.

13 MS. GERSTEL: Okay.

14 (Recess taken.)

15 (Lind Exhibit 17, e-mail chain
16 ending May 10, 2010, Bates No.
17 HMESH_ETH_03111719, was marked for
18 identification, as of this date.)

19 BY MR. DeGREEFF:

20 Q. Sir, I've just handed you what

21 I've marked Deposition Exhibit 17.

22 Do you see that?

23 A. Yep.

24 Q. This is some e-mail exchanges

328

1 from April of 2010.

2 Correct?

3 A. These are e-mails from 2010,
4 yes.

5 Q. And the first e-mail on the
6 chain is an e-mail that you sent to
7 Vincenza Zaddem.

8 Right?

9 A. I reviewed the contract.

10 Q. At you just look at the to/from
11 line and the e-mail.

12 A. Yeah. I see the one with me to
13 Zaddem, yes.

14 Q. And who is Zaddem?

15 A. I don't know.

16 Q. Really my only question is if
17 you look at that, you say: I reviewed the
18 contract.

19 Correct?

20 A. Yes.

21 Q. And then under item 17, the
22 paragraph that starts with the words "item
23 17," the last sentence is: The value of
24 the contract does not justify exclusive

329

1 services.

2 Did I read that correctly?

3 A. Yes.

4 Q. What was the value of this
5 contract?

6 MS. GERSTEL: Objection.

7 A. The value of the contract had
8 standard terms of just hourly rate for --
9 for work done. It entire set -- this
10 entire conversation is about what we were
11 eluding to before insofar as I do
12 consulting with other companies on
13 incontinence and prolapse. The way that
14 they had the contract written, I wouldn't
15 be able to work with anyone else on
16 incontinence and prolapse so, what I was

17 telling them was that you need to, as you
18 have in the previous one where it says the
19 contract must be limited to anchoring
20 devices for prolapse, something specific
21 that we're working on that makes it
22 specific to what I'm doing for Ethicon,
23 because I couldn't sign the contract
24 because it made it so I couldn't work with

330

1 anyone else. It wasn't like I was being
2 offered \$40,000 or some big sum to have an
3 exclusivity arrangement.

4 What I meant by exclusive
5 services meaning exclusive of other
6 companies. That's just a standard
7 contract. Didn't work.

8 So, you know, I remember this
9 freshly now. We went back and forth, back
10 and forth. And they said, Everyone just
11 signs theses. I said, Well, maybe
12 everyone doesn't read it. If your
13 contract says I can't work with anyone
14 else, then I won't work with anyone else.

15 So if you want me to look at these
16 anchoring devices, which is what they
17 wanted me to do, then make the language
18 for the anchoring device, but don't make
19 it to cover that you can't work on anyone
20 else for anything else that you do.

21 So really it was just the
22 wording of their contract meant that I
23 could work with anyone on incontinence and
24 prolapse, and I was asking them to make a

331

1 contract that was just specific to what
2 they wanted me to look at, which was an
3 anchoring device.

4 Q. And these amounts you're being
5 paid for consulting work, that's above and
6 beyond what you're being paid as a
7 physician.

8 True?

9 A. Yes. With the only
10 clarification to make when we went to
11 the -- when we were doing the study, the
12 study payments are a hundred percent paid

13 to the hospital research fund, and there's
14 no compensation part out of that for me.

15 Q. Okay.

16 And what amount would have
17 justified exclusivity?

18 A. I actually -- it's -- I wouldn't
19 do that. I think with -- you've just gone
20 through a whole bunch of papers showing
21 that I've worked with a lot of different
22 companies on consulting arrangements, and
23 what I'll tell you is that when I have an
24 idea and I find the person I can work with

332

1 on it, I go there. So it's not a matter
2 of trying to just make money off of
3 everyone. There's different opportunities
4 at different times with different
5 companies are ready for different ideas.
6 So -- so, I never considered an exclusive
7 agreement with anyone, which is why I
8 couldn't tested the wording in the
9 contract.

10 Q. Everything we've gone through, I

11 mean, you've been paid over half a million
12 dollars as on behalf of the transvaginal
13 mesh world, if you will.

14 Right?

15 MS. GERSTEL: Objection.

16 BY MR. DeGREEFF:

17 Q. The manufacturers?

18 MS. GERSTEL: Objection.

19 MR. DeGREEFF: Strike that.

20 I'll reword that.

21 BY MR. DeGREEFF:

22 Q. Based on everything we've been
23 through, you've been paid over a half
24 million dollars by transvaginal mesh

333

1 manufacturers.

2 True?

3 MS. GERSTEL: Objection.

4 A. I don't know if that's accurate.

5 It's definitely in the hundreds of
6 thousands. I don't know how many it is.
7 I would have to be -- I don't know how
8 many occasions I saw each of these

9 Gynecare contracts. I don't have the
10 listed payments for. There's a lot of
11 years of contracts, and I'm not sure how
12 frequent those were.

13 Q. Well, when you add in what
14 you've been paid as an expert witness,
15 it's pretty clear you've been paid over a
16 half million dollars by the transvaginal
17 mesh industry.

18 Right?

19 MS. GERSTEL: Objection.

20 A. You may have been adding those.
21 Somewhere between three hundred and six
22 hundred I would agree with somewhere in
23 there. I just don't want to agree to a
24 number that I haven't quantified with a

334

1 little more conviction.

2 MR. DeGREEFF: I've handed you
3 what's been marked as Deposition
4 Exhibit 18.

5 (Lind Exhibit 18, Master
6 Consulting Agreement between Lawrence

7 Lind and Ethicon, Inc. Dated July 10,
8 2010, Bates No. ETH.MESH.06216861 to
9 06216869, was marked for
10 identification, as of this date.)

11 BY MR. DeGREEFF:

12 Q. Sir, do you see that this is a
13 master consulting agreement between you
14 and Ethicon?

15 A. Right.

16 Q. And it's dated July 10th --
17 well, it says it commences July 10th of
18 2010 and continues through December 31st
19 of 2011?

20 A. Right.

21 Q. My question is if you look at
22 where it's Bates numbered '868 at the
23 bottom?

24 A. Okay.

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1 Q. This talks about the fact that
2 you're being retained, the box where it
3 says yes, you're being retained at a rate
4 of \$437.50 per hour.

5 Correct?

6 A. That's what it says.

7 Q. And it lays out the description
8 of your services and the fact that it will
9 be an estimate of 120 hours of work
10 maximum over the life of this contract?

11 A. That's what it says.

12 Q. And that's estimate, obviously.

13 A. Yes.

14 Q. And then it says: The parties
15 agree that compensation paid to consultant
16 shall not exceed \$52,500 per contract
17 term.

18 A. Right.

19 Q. Did I read that correctly?

20 A. Yes.

21 Q. And the contract term was a
22 little over a year.

23 Is that right?

24 A. Yes.

336

1 Q. Were you paid this full \$52,500?

2 A. I would strongly doubt that in

3 2010.

4 Q. If you could look at the next
5 page. I guess they were authorizing you
6 to be paid 52,500 for the year under this
7 contract.

8 Right?

9 A. They were offering that to be a
10 max based on the hourly fee.

11 Q. If you look at Exhibit B, this
12 titled Conflict of Interest Certification?

13 A. Yeah.

14 Q. And it states, and this is
15 supposed to be from you.

16 Correct?

17 MR. DeGREEFF: Let's do this.

18 This one is unsigned. So let's give
19 you this one.

20 Sir, I'm going to what kind you
21 what's been marked as deposition
22 Exhibit 19.

23 (Lind Exhibit 19, Master
24 Consulting Agreement between Lawrence

1 Lind and Ethicon, Inc. Dated August
2 31, 2010, Bates No. ETH.MESH.02030557
3 to 02030566, was marked for
4 identification, as of this date.)

5 BY MR. DeGREEFF:

6 Q. Deposition Exhibit 19 is another
7 master consulting agreement between you
8 and Ethicon.

9 Correct?

10 A. Right.

11 Q. And it's dated -- it says it
12 commences August 31st of 2010 and
13 continues through December 31st of 2011.

14 Right?

15 A. Yeah. This is kind of confusing
16 that they have like fresh contracts every
17 month. But be that as it may.

18 Q. Right.

19 And this contract is signed by
20 you.

21 Correct? Bates number '562.

22 A. Yes.

23 Q. Then if you look at Bates number
24 '564, this has the same language about

1 payment to you.

2 Correct?

3 MS. GERSTEL: Objection.

4 A. Right.

5 Q. Again you're being paid \$437.50
6 an hour?

7 A. Yep.

8 Q. And you've got another maximum
9 cap of \$52,500 per contract term?

10 A. Correct.

11 Q. Again, that contract term is a
12 little over a year?

13 A. Okay.

14 Q. Is that correct?

15 A. Yes.

16 Q. Then if you look at the next
17 page, it's got an Exhibit B titled
18 Conflict of Interest Certification.

19 Correct?

20 A. Right.

21 Q. And that is signed by you?

22 A. Yes.

23 Q. And that includes language that

24 states: In assuming contractual

339

1 obligations to Ethicon Inc., the
2 undersigned health care professional.

3 That's you, right?

4 A. Yes.

5 Q. Agrees that financial ties
6 between the health care professional and
7 industry may create conflicts of interest,
8 both real and perceived.

9 Did I read that correctly?

10 A. Yes.

11 Q. This is essentially Ethicon
12 acknowledging that payments to physicians,
13 such as --

14 MR. DeGREEFF: Strike that.

15 Q. This is Ethicon acknowledging
16 that payments to physicians can create
17 conflicts of interest.

18 Right?

19 MS. GERSTEL: Objection.

20 A. Got it.

21 Q. Is that correct?

22 MS. GERSTEL: Objection.

23 A. Which sentence are you reading
24 again?

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1 Q. Where it states: The
2 undersigned health care professional
3 agrees that financial ties between the
4 health care professional and industry may
5 create conflicts of interest, both real
6 and perceived?

7 A. Okay. I agree. I agree that's
8 what it says.

9 Q. And is this essentially Ethicon
10 acknowledging that payments to physicians
11 can create conflicts of interest?

12 MS. GERSTEL: Objection.

13 A. That they may create conflicts
14 of interest, yes.

15 Q. We just talked about you've been
16 paid between three hundred and 600,000 by
17 the transvaginal mesh industry.

18 Right?

19 MS. GERSTEL: Objection.

20 A. By estimates, it seems it would
21 be in that range.

22 Q. And you've been a consultant for
23 four transvaginal mesh companies.

24 Right?

341

1 A. Yes.

2 Q. You've been a consultant for
3 Ethicon.

4 Right? True?

5 A. Yes.

6 Q. Caldera?

7 A. Yes.

8 Q. Boston Scientific?

9 A. Yes.

10 Q. AMS?

11 A. Yes.

12 Q. And you've been referred to as a
13 key opinion leader for Ethicon products by
14 internal Ethicon employees.

15 Right?

16 A. Yes.

17 Q. And you've been referred to as

18 having a marketing contract with Ethicon
19 by Ethicon employees.

20 Right?

21 A. Referred to, yes.

22 Q. And we've looked at multiple
23 consulting agreements that you've signed
24 with Ethicon.

342

1 True?

2 A. Yes.

3 Q. And you've signed a conflict of
4 interest statement from Ethicon based on
5 the fact that payments to health care
6 providers can create conflicts of
7 interest, both real and perceived.

8 Right?

9 A. Correct.

10 Q. Despite all of that, you were
11 ultimately hired by Ethicon to act as a
12 expert in this litigation.

13 Right?

14 MS. GERSTEL: Objection.

15 A. I'm not sure why it's despite

16 this. But I was hired by Ethicon to be in
17 this role that I am now.

18 I'm not sure how your one thing
19 with the word despite, I'm not sure how
20 that fits into the question.

21 Q. You've now been hired by Ethicon
22 to serve as an expert in this transvaginal
23 mesh litigation.

24 Right?

343

1 A. Yes.

2 Q. And do you have any
3 understanding of why Ethicon did not get a
4 physician who did not have a consulting
5 agreement with prior to hiring them as an
6 expert witness in the litigation?

7 MS. GERSTEL: Objection; lack of
8 foundation.

9 A. I would be conjecturing. I
10 don't have factual knowledge.

11 Is there a question on this?

12 Q. We had several questions on it.

13 A. Okay.

14 MR. DeGREEFF: Last I want to
15 show you deposition Exhibit 20. I so
16 marked that.

17 (Lind Exhibit 20, EWHU HCP
18 Cognos report run 11/17/10, was marked
19 for identification, as of this date.)

20 BY MR. DeGREEFF:

21 Q. If you look at the second page,
22 you'll find your name towards the bottom.

23 A. Okay.

24 Q. This shows two separate -- this

344

1 reflects the two separate contracts of
2 52,500.

3 Correct?

4 A. Right.

5 Q. For a total of 105,000?

6 A. Right.

7 Q. So you had been authorized by
8 Ethicon for up to \$105,000 of payment for
9 a little over a year.

10 Right?

11 MS. GERSTEL: Objection.

12 A. I think this is misleading. The
13 maximal allowed in the contract was that
14 amount, and this reflects nothing in the
15 way of what I actually received.

16 Q. That wasn't my question.

17 You were authorized by Ethicon
18 for up to \$105,000 worth of payment in one
19 year.

20 Right?

21 MS. GERSTEL: Objection.

22 A. If I worked \$437 an hour to get
23 to \$105,000.

24 Q. For if they wanted pay you

345

1 \$3,000 to show up to a lecture.

2 Right?

3 MS. GERSTEL: Objection.

4 A. The contract had an hourly rate.

5 Q. Okay.

6 Why was there two different
7 agreements? Did you use all of one of
8 them?

9 MS. GERSTEL: Objection.

10 A. It looks to me like on the first
11 one I hadn't signed the institutional
12 compliance that I -- that my working for
13 them did not violate institutional
14 compliance for doing consulting work. So
15 one of them had a signature and one of
16 them did not. So I think they sent a
17 whole new contract to have me sign that
18 last page, is what I -- it looks like to
19 me from the two.

20 Q. Why does this spreadsheet
21 reflect that you had two separate --

22 MS. GERSTEL: Objection.

23 A. Well, we looked at two separate
24 ones and you'll see -- one of them the

346

1 last page is not signed and one of them
2 the page is signed. So they made two
3 contracts for that amount. I'm guessing
4 that the first one they considered to be
5 legally not binding because I didn't sign
6 that required field and they made another
7 one and it's showing up on here because

8 two contracts were drawn. But it's --
9 it's line items on a spreadsheet. I can't
10 account for them. I can -- I am one
11 thousand percent sure I didn't come
12 anywhere close to this kind of money from
13 2010 on with Ethicon.

14 Q. That assumption is based on --
15 what you just said requires us to assume
16 that we have received all of the documents
17 that we would need to show the signing of
18 that contract.

19 Correct?

20 MS. GERSTEL: Objection.

21 A. Yeah, I agree. We don't right
22 now between us have the accounting
23 accurate payroll of what was paid. But
24 just knowing what I was doing with time in

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1 2010 onward, I feel fairly confident, but
2 I don't have your objective proof, that I
3 came nowhere near that, but I am very
4 confident of that.

5 Q. Is there a single long-term

6 randomized controlled trial specifically
7 addressing the TVT-0?

8 A. TVT-0 has in the range of 40 to
9 50 randomized trials. I'd have to go
10 through them to figure out how far the
11 long-term is.

12 Q. What about a single randomized
13 control trial specifically addressing the
14 TVT-0 with safety as the primary endpoint?

15 MS. GERSTEL: Objection.

16 A. Safety is a primary endpoint in
17 many of the randomized controlled studies.
18 Whether they listed efficacy first and
19 safety as second, I would have to go
20 through each report, but safety was
21 reported in a very large number of them.

22 I will agree that in some of
23 them the adverse events data was not
24 accurately reported, which is why we rely

348

1 on Cochrane and excellent meta-analysis so
2 that they include studies that have the
3 data we need.

4 Q. What is your definition of
5 primary endpoint? Because I think it may
6 be different than mine.

7 A. Primary endpoint is the first
8 and -- first priority end point result
9 you're looking for in a study.

10 Q. Right.

11 And you think there's a single
12 long-term randomized study out there with
13 safety as the primary endpoint on the
14 TVT-0 product?

15 A. I don't think it's as a primary
16 endpoint because it's pretty traditional
17 to do efficacy and then safety. But a
18 second endpoint doesn't diminish its
19 value, statistical value.

20 Q. So the answer to my question as
21 asked is no.

22 Right?

23 MS. GERSTEL: Objection.

24 A. I would have to look through all

349

1 the randomized studies to do that. I

2 don't know that offhand.

3 Certainly most of them don't
4 have it as the primary.

5 Q. What about is there a single
6 randomized controlled trial with safety as
7 the primary endpoint that specifically
8 addresses the TVT-Abbrevio?

9 MS. GERSTEL: Objection.

10 A. I think your primary endpoint is
11 a -- from the challenging the data on this
12 as a primary endpoint is on the verge of
13 incredible.

14 Q. Okay. I appreciate your
15 thoughts on that. I really do.

16 MR. DeGREEFF: And I'll move to
17 strike it. But I do want an answer to
18 my question.

19 A. I would have to review each of
20 them to see which ones have primary
21 endpoints. I don't know off the top of my
22 head if they have primary endpoints. So I
23 don't know the answer to that question.

24 Q. And then same question for

1 TVT-Exact, is there a single long-term
2 randomized controlled trial with safety as
3 the primary endpoint specifically
4 addressing the TVT-Exact?

5 A. That one I think I could tell
6 you is no.

7 Q. Is there a single long-term
8 randomized controlled study with safety as
9 the primary endpoint that looks at the
10 TVT?

11 MS. GERSTEL: Objection.

12 A. I'd have to look at the -- each
13 randomized study. I can't answer that off
14 the top of my head.

15 Q. There's not one you could think
16 of?

17 A. Not off the top of my head.

18 Q. Ethicon has never done a study
19 with the primary endpoint was to determine
20 where or not laser-cut mesh is stiffer or
21 safer than mechanical-cut mesh.

22 Right?

23 MS. GERSTEL: Objection.

24 A. I seem to recall there being

1 some internal study of the laser-cut mesh.
2 I can't recall all the details on it, but
3 I think they did study the properties. If
4 I recall, and again it's off the top of my
5 head, I would have to find the document.
6 I think it was determined that they felt
7 it would not be a significant difference.

8 Q. Are you talking about testing or
9 a study?

10 MS. GERSTEL: Objection.

11 A. Mechanical testing.

12 Q. I'm talking about a study.

13 Ethicon's never done a study
14 where the primary endpoint is to determine
15 whether or not laser cut mesh is stiffer
16 and less safe than mechanical-cut mesh.

17 Correct?

18 MS. GERSTEL: Objection.

19 A. A study in humans? What type of
20 study.

21 Q. Any kind of study.

22 A. Well, a lab is a study.

23 Q. Well, lab's a benchtop, right?

24 A. A study is when you investigate

352

1 to find answers. It doesn't matter what
2 location it's in, whether it's a lab or in
3 a human. It can be a study.

4 Q. I think you and I define a study
5 different.

6 You're talking about benchtop
7 testing.

8 Right?

9 A. I'm talking about comparing
10 properties. You compare one thing against
11 another is the definition of a study.

12 Q. So anything that's ever done at
13 Ethicon is a study, even if they're just
14 doing it on a bench?

15 MS. GERSTEL: Objection.

16 A. Well, if we're just chatting
17 about the study, it's not a study. If
18 they have two products and they're
19 comparing how it behaves in different
20 circumstances, that's a study.

21 Q. So, I guess can you answer my
22 question or not?

23 And my question is Ethicon has
24 never done a study where the primary

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1 endpoint is to determine whether or not
2 laser-cut mesh is stiffer and less safe
3 than mechanical-cut mesh?

4 MS. GERSTEL: Objection.

5 BY MR. DeGREEFF:

6 Q. True?

7 MS. GERSTEL: Asked and
8 answered.

9 A. If I'm recalling correctly, and
10 I cannot put my reputation on it, I think
11 the bench work study that they did looked
12 at stiffness, but they couldn't, by that
13 study, evaluate safety.

14 Q. We talked earlier about the
15 Ethicon employees' e-mails about concerns
16 about the outcomes related to stiffness of
17 the mesh.

18 Right?

19 MS. GERSTEL: Objection.

20 A. We had that discussion, I do
21 recall.

22 MR. DeGREEFF: I'm good. We can
23 be done.

24 MS. GERSTEL: I have like five

354

1 minutes.

2 Do you want to take a break, or
3 should I just start?

4 MR. DeGREEFF: Go for it.

5 MS. GERSTEL: I know we're all
6 running on fumes.

7 EXAMINATION

8 BY MS. GERSTEL:

9 Q. Dr. Lind, you were asked some
10 questions about the Advantage Fit Boston
11 Scientific sling that you had a role in
12 developing.

13 Is that correct?

14 A. Yes.

15 Q. Is it your opinion, despite that
16 role in developing the Advantage Fit

17 sling, that retropubic TVT is the gold
18 standard?

19 MR. DeGREEFF: I'm going to
20 object to form.

21 BY MS. GERSTEL:

22 Q. For surgical treatment of stress
23 urinary incontinence in women?

24 A. Yes.

355

1 Q. Did the vast majority of your
2 patients have excellent results with
3 retropubic TVT?

4 MR. DeGREEFF: Object to form.

5 A. Yes.

6 Q. And, doctor, you were asked some
7 questions regarding Abbrevio being a
8 shorter sling than TVT-0 and TVT-Exact.

9 Do you recall that?

10 A. Yes.

11 Q. Is it correct that even though
12 Abbrevio is not as long as a TVT-Exact or a
13 TVT-0 or a retropubic TVT that it is not a
14 mini sling?

15 MR. DeGREEFF: Object to form.

16 A. I agree with that.

17 MR. DeGREEFF: You want to just
18 give me an ongoing objection to
19 leading?

20 MS. GERSTEL: Yes. Although I
21 disagree that was leading.

22 MR. DeGREEFF: Well, you can't
23 testify for him.

24 MS. GERSTEL: I'm not testifying

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1 for him.

2 MR. DeGREEFF: That's what
3 you're doing right now.

4 MS. GERSTEL: I am not
5 testifying for him. I asked him --

6 MR. DeGREEFF: I'll just keep
7 objecting. That's fine.

8 BY MS. GERSTEL:

9 Q. Doctor, you were asked some
10 questions regarding your own experience
11 and results treating patients with TVT-0,
12 TVT-Exact and TVT-Abbrevio.

13 Is that correct?

14 A. Yes.

15 Q. Is your own experience with
16 TVT-0, TVT-Abbrevio and TVT-Exact
17 consistent with what you have opined on as
18 to the safety and efficacy of those
19 products as based on the highest levels of
20 medical literature?

21 MR. DeGREEFF: Object to form.

22 A. Yes.

23 Q. Doctor, you were asked some
24 questions about what you have and have not

357

1 reviewed --

2 MS. GERSTEL: Strike that.

3 Q. Doctor, you were asked some
4 questions regarding your supplemental
5 materials list.

6 Correct?

7 A. Yes.

8 Q. And you were asked some
9 questions regarding which of the documents
10 on that list you had or had not reviewed.

11 Correct?

12 A. Yes.

13 Q. Doctor, is it true that you read
14 many, many medical articles and company
15 documents and depositions and other such
16 materials sense you began your expert work
17 with Ethicon?

18 MR. DeGREEFF: Object to form.

19 A. Yes.

20 Q. As you sit here today, is it
21 true that you may or may not recall
22 specific documents that you have reviewed
23 that are listed on your materials list?

24 MR. DeGREEFF: Object to form.

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1 A. That's true.

2 Q. And is that particularly true if
3 you weren't shown the document when asked
4 if you had or had not reviewed them?

5 MR. DeGREEFF: Object to form.

6 A. Yes.

7 Q. I think that this was adequately
8 covered by plaintiff's counsel's

9 questioning.

10 But, doctor, were you asked some
11 questions regarding whether you had --

12 MS. GERSTEL: Well, strike that.

13 Q. Doctor, earlier in this
14 deposition you testified regarding closer
15 analysis that you have done recently of
16 the Schimpf, Teo and Okulu articles.

17 Is that correct?

18 A. Yes.

19 Q. After that closer analysis of
20 those articles, did your opinions as
21 expressed in your report that's been
22 marked as Exhibit 8, did your opinions
23 change as a result of that closer analysis
24 of those articles?

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1 A. It didn't. It became
2 strengthened with regards to the safety
3 profile of the TVT-0.

4 MS. GERSTEL: That's all I have.

5 MR. DeGREEFF: I just have two
6 questions.

7 FURTHER EXAMINATION

8 BY MR. DeGREEFF:

9 Q. Which device did you agree with
10 counsel was the gold standard device?

11 A. I would say the retropubic TVT
12 as well as the TVT-0.

13 Q. Okay.

14 Why are you not using the gold
15 standard device?

16 MS. GERSTEL: Objection.

17 A. I do use the TVT-Exact, which I
18 consider to be the extremely similar
19 device with a modification that I like,
20 which is a narrower shaft.

21 Q. You use it in one out of ten of
22 your patients?

23 A. Right.

24 Q. Why would you not use the gold

360

1 standard device in all of your patients?

2 MS. GERSTEL: Objection.

3 A. Because there was a -- there was
4 a decision at one point to bring on

5 Caldera for financial reasons. At that
6 point, we were asked to convert over to
7 that and see if it met our needs. It met
8 my needs, and I like the flexibility, and
9 I started using it for good fraction of my
10 cases.

11 Q. Are you breaching the standard
12 of care by not using the gold standard
13 device?

14 MS. GERSTEL: Objection.

15 A. I'm using an FDA-approved device
16 that I feel is excellent for its intended
17 purposes, and it's been performing well
18 for several years.

19 Q. Yes or no, you are not using
20 what you just testified is the gold
21 standard device.

22 Correct?

23 MS. GERSTEL: Objection.

24 A. I'm using the TVT-Exact in one

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1 tenth of my cases, yes.

2 Q. In 90 percent of your cases, you

3 are not using the device you have just
4 testified is the gold standard device.

5 Right?

6 MS. GERSTEL: Objection.

7 A. Correct.

8 Q. You were asked by your counsel
9 if --

10 MR. DeGREEFF: Strike that. It
11 doesn't matter.

12 All right. I'm done.

13 MS. GERSTEL: I just have one
14 follow-up.

15 FURTHER EXAMINATION BY

16 MS. GERSTEL:

17 Q. Doctor, this isn't a document
18 that we have marked as an exhibit in this
19 deposition, but are you familiar with the
20 AUGS SUFU position statement on
21 midurethral slings?

22 A. Actually, I need it -- I think I
23 answered incorrectly on your last
24 question.

1 MR. DeGREEFF: Well, we've got a
2 different question pending now. So if
3 your counsel wants to clear something
4 up with you, she can ask you a
5 question.

6 THE WITNESS: It has to do with
7 the gold standard.

8 MS. GERSTEL: Go ahead.

9 MR. DeGREEFF: No, she can ask
10 you a question if she wants to ask you
11 something about it.

12 BY MS. GERSTEL:

13 Q. Doctor, what were you going to
14 say?

15 MR. DeGREEFF: I'm going to
16 object to the form. That's open-ended
17 and allows for a narrative response.

18 A. Well, the TVT by Ethicon has the
19 preponderance of the data. The
20 meta-analyses that go over all the slings
21 and all the data for slings certifies
22 polyester synthetic midurethral slings as
23 the gold standard of care. The
24 meta-analysis do not specify Gynecare TVT

1 as the standard of care. So, Ford and
2 Cochrane specify that tapes that pass in
3 the obturator pathway and in the
4 retropubic pathway and then they give
5 their -- they give their affirmation and
6 every authoritative agency that's
7 approving and ratifying midurethral slings
8 as the standard of care ratifies
9 midurethral slings. So, it is while
10 the -- I would certainly agree that the
11 largest amount of data on midurethral
12 slings comes from Ethicon, the number of
13 time and decades and years and studies
14 that have proven that the result are
15 similar make it a midurethral sling
16 appeared not necessarily a Gynecare TVT
17 midurethral sling which is the standard of
18 care.

19 So in that regard, I continue to
20 use the standard of care.

21 MR. DeGREEFF: Okay. I'm going
22 to ask a follow-up question. I'll let
23 your counsel finish.

24 MS. GERSTEL: Okay.

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1 BY MS. GERSTEL:

2 Q. Doctor, I think you anticipated
3 what my question was going to be.

4 First, doctor, I believe that
5 you just misspoke now when you said
6 polyester.

7 Did you mean polypropylene?

8 A. Yes.

9 Q. And, doctor, I'll just re-ask
10 that question.

11 Are you familiar with the AUGS
12 SUFU position statement on mesh
13 midurethral slings?

14 A. Yes.

15 Q. And does that position statement
16 refer to polypropylene type 1 macroporous
17 mesh midurethral slings regardless of
18 root, transvaginally or retropubic, as the
19 gold standard in surgical treatment for
20 stress urinary incontinence in women?

21 A. Yes, it does.

22 Q. And do you agree with that
23 opinion?

24 A. I do.

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1 MS. GERSTEL: That's all I have.

2 MR. DeGREEFF:

3 FURTHER EXAMINATION

4 BY MR. DeGREEFF:

5 Q. Doctor, you are now withdrawing
6 your earlier statement that the TVT
7 products are the gold standard.

8 Correct?

9 MS. GERSTEL: Objection.

10 A. I would say based on the
11 meta-analysis, yes.

12 Q. What your testimony is is that
13 you believe midurethral slings to be the
14 gold standard.

15 Right?

16 A. Yes.

17 MR. DeGREEFF: No further
18 questions.

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